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Summary of adverse drug reaction reports in Sweden with Pandemrix (received up to November 10)

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As of today, about 2.1 million doses of Pandemrix have been distributed in Sweden. In total, almost six hundred adverse drug reaction (ADR) reports have been received by the MPA from Health Care Professionals and close to 900 reports from Consumers. The ADR reporting pattern is generally consistent with the expected pattern seen previously in the clinical trials. In this compilation of ADRs reported in Sweden with Pandemrix, allergic reactions, neurological reactions and reactions in children are specifically addressed.

As stated in previous communications, it should be remembered that all ADR reports should be considered as part of a larger pattern and that it rarely can be concluded from a single report if the reaction was caused by the vaccine or not. It is therefore important to stress the following:

- The reports describe reactions that have occurred in close connection to when the vaccine was given.
- The reaction can thus be caused by the vaccine, but can also be signs of illness the patient suffered from regardless of the vaccination.
- Causality assessment can only be made after the report has been carefully assessed.

Since the vaccination campaign began, the MPA has published summaries of adverse events reported with Pandemrix. The summaries are focused on reports relating to unknown and suspected serious side effects while the known adverse events are reported only briefly. All reports are reviewed and assessed, however, in the usual manner.

Reports from Health Care Professionals

Almost 600 reports have been received from health care professionals.

The majority of the adverse events are expected and known reactions such as soreness, redness and pain at the injection site and in the arm, and flu-like symptoms such as fever, shivering, fatigue, moderate/severe headaches, body aches and malaise. Experiences from certain vaccination sites point to the fact that these expected reactions have been very common. In a fewer number of reports, symptoms of nausea, vomiting, stomach pain, diarrhoea, dizziness, rashes and insomnia are reported. All these reactions are known from the studies performed on Pandemrix. Also a number of allergic reactions have been reported (see below).

Allergic reactions

In 76 patients, 137 adverse events have (up to November 10) been reported suggestive of allergic reactions associated with vaccination with Pandemrix (see Table 1). Several of the patients with a severe hypersensitivity reaction had known allergies to pollen, grass, medicines, certain foods such as eggs, nuts, fruit, peanuts, fish, etc. In most of the cases deemed serious, the patients needed treatment with antihistamines, adrenaline and cortisone and supervision in hospital. In all cases, the hypersensitivity reactions have resolved rapidly and completely.

Two cases of anaphylactic shock have been reported. In one case the patient had a known egg allergy; the other patient was allergic to several foods, including nuts, but not to eggs.

The reports on allergic reactions shows that not only allergy to substances in the vaccine such as egg gives rise to reactions, but also other forms of allergic tendency seems to be able to contribute to an allergic reaction. This must be taken into consideration before vaccination.

Table 1: Allergic reactions

Reaction	Known allergy (no of patients)	Serious reactions	Non serious reactions	Total no of reported reactions
Allergic reaction	12	4	14	18
Anaphylactic reaction	6	11	1	12
Anaphylactic shock	2	2		2
Angiooedema	1	5	8	13
Oedema in mouth and throat	1	1	9	10
Urticaria	1	1	20	21
Exanthema			12	12
Flush	2	1	8	9
Itching	4	1	16	17
Astma - worsened	1	1	4	5
Dyspnoea	2	4	14	18
Total	32	31	106	137

Neurological reactions

In 133 patients, 177 neurologic adverse events have been reported. Many of these reactions may be part of the syndrome of allergic reactions (e.g. dizziness, headache). 32 adverse events reports represent hypotension/fainting, sometimes described with other associated neurological symptoms such as dizziness, taste- or visual disturbance or absence attack. 44 cases of sensory changes are reported, they vary from local pain and/or numbness in the vaccinated arm, sometimes extending to the face, to a couple of cases of numbness throughout the vaccinated half of the body. Sensory changes generally disappeared within a day except for local reactions at the injection site which in some cases have lasted for several days.

Four cases of facial palsy or facial palsy like symptoms are reported, in three women and one man. In one of the cases, the reaction is reported in a child with suspected *Borrelia* infection as a triggering cause (the symptoms improved after treatment of the *Borrelia* infection (Lyme disease)). One case involves a pregnant woman with mild symptoms that improved within a few days. In two cases, the facial palsies are reported in connection with flu-like symptoms after vaccination and in these individuals the symptoms subsided within 10 hours or three days respectively. These reports are still under investigation and there will be further follow-up.

Two cases of stroke, one fatal, are reported, 3 and 4 days after vaccination respectively. There is nothing to support a casual association between the vaccination and the deaths.

Facial palsy is a unilateral weakness/paralysis of facial muscles. It can be caused by damage to the facial nerve or an injury of the brain. The cause of peripheral facial palsy, Bell's palsy, is in most cases unknown but may be caused by certain infections, e.g. *Borrelia*, varicella-zoster virus or herpes simplex virus. It is also more common in pregnant women. Most of the cases resolve within a few months without residual symptoms. In Sweden 50 individuals per week are diagnosed with facial palsy. By now close to 1/4 of the population is estimated to have been vaccinated, thus the number of reported cases is within what could be expected.

Reactions in children

In Sweden (up to November 5) about 5000 children, less than 3 years of age and who belong to risk groups, have been vaccinated. Moreover, close to 50 000 children aged 3-6 years (both risk groups and healthy children) have been vaccinated. Of the 500 adverse event reports received from Health Care Professionals, 31 relate to children born in 2000 or later. Only 5 reports concern children less than 3 years. The ADR reporting pattern does not differ from what has been seen in older children (see Table 2).

In light of the reports of allergic reactions received, the vaccination of children with egg allergy, other severe allergy or with severe allergy in the immediate family should only take place after consultation with a specialist.

Table 2: Adverse event reports received from Health Care Professionals and related to children born in 2000 or later

	Born	Age	Sex	Diagnosis

1	-07	2	m	Fever
2	-07	2	f	Nausea
3	-07	2	f	Local reaction at injection site
4	-07	2	m	Absence attacks
5	-06	2	m	Collapse
6	-06	3	m	Arthritis
7	-06	3	m	Syncope, local reaction
8	-06	3	f	Skin rash
9	-06	3	m	Fever, abdominal pain
10	-05	4	m	Nausea
11	-05	4	f	Abdominal pain, Nausea
12	-05	4	f	Bell's palsy (facial palsy)
13	-04	4	f	Pain
14	-04	5	f	Nightmares
15	-04	5	m	Urticaria
16	-04	5	f	Flu-like symptoms
17	-04	5	f	Fever, headache, visual disturbance
18	-04	5	m	Varicellae, nightmares
19	-03	5	m	Presyncope
20	-03	5	m	Hypersensitivity reaction (skin rash)
21	-03	6	f	Fever, nausea o vomiting
22	-02	7	m	Abdominal pain
23	-02	7	f	Urticaria
24	-02	7	m	Syncope
25	-02	7	m	Fever, nausea, abdominal pain, body aches
26	-01	8	m	Headache, nausea
27	-00	8	m	Angiooedema

28	-00	9	m	Pain and tightness of the chest
29	-00	9	f	Nausea, abdominal pain
30	-00	9	f	A little pale, the day after
31	-00	9	m	Urticaria

Deaths reported

A cumulative total of 8 reports of death have been received, all of which have had a temporal association with vaccination. The time between the vaccination and the death has varied between 12 hours and 4-5 days. These eight patients all had previously known chronic diseases such as cardiovascular disease, pulmonary disease, diabetes, renal failure, dystrophic muscle disease and senile dementia. All patients were on chronic medical treatment. Autopsy results are available for four of the cases and in all these cases a relation between the vaccination and the death is considered unlikely. For the other cases there is insufficient information and autopsy protocols are lacking which limits the assessment. These reports are still under investigation and further information will be sought, but from what has emerged so far there is nothing to confirm a causal association between the vaccination and the death.

In assessing the number of reported deaths, it is - as mentioned in previous compilation - important to take into account that in Sweden on average 200-250 deaths occur per day and at present a large proportion of the population, particularly the elderly and other risk groups, are being vaccinated. The majority of deaths occurring daily in Sweden are older people with complications of chronic diseases.

Experience from consumer reporting

Since the vaccination campaign with Pandemrix started on October 12, 2009, the MPA has received close to 900 consumer reports. A large majority, about 90% of reports, describe non-severe, expected and known reactions. The potentially serious cases are similar to the serious reactions reported by Health Care Professionals. These include one case of facial palsy in a young man, cases of severe influenza-like illness, and allergic reactions. In addition, one fatal case has been reported with a temporal association with the vaccination. Insufficient information limits the assessment of this case and additional data from the health care has been requested.

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