

# Summary of adverse drug reaction reports in Sweden with Pandemrix

Thursday, October 29, 2009

As of today, about 1.4 million doses of Pandemrix have been distributed in Sweden. In total, about two hundred adverse drug reaction (ADR) reports have been received by the MPA from Health Care Professionals and between 400-500 reports from consumers. The ADR reporting pattern does not deviate from what has been seen in the clinical trials. However, there is particular reason to follow reports of allergic reactions.

It should be remembered that all ADR reports should be considered as part of a larger pattern in which one single report rarely means that an adverse reaction was caused by the vaccine. It is 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. MPA will continue to review and assess all reports, but the published compilations will mainly focus on reports relating to unknown and serious suspected adverse reactions, while the presentation of reports on the known side effects are reported only briefly.

## Reports from Health Care Professionals

Almost 200 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).

## Comments on some case reports

About 20 reports of the suspected adverse reactions have been identified as serious and with a causal relationship to the vaccination. Allergic adverse reactions represent the majority of these reports, see table below. Besides these, facial palsy (one case), paresthesia (three cases), sensibility disorder (one case), hypertension (one case), and absence attacks (one case) were reported.

## Allergic reactions/ allergic symptoms reported in relation to administration of

Pandemrix

Included in SWEDIS data base 12 Oct - 27 Oct, 2009

	Related serious)	(of which were	Not related
Allergic reaction	10	(3)	2
Anaphylactic reaction	5	(5)	1
Angiooedema	5	(3)	0
Urticaria	6	(2)	0
Exanthema	2	(0)	1
Flush	3	(0)	0
Swollen tongue	2	(0)	1
Dyspnoea	7	(2)	1
Cough	1	(0)	0
TOTAL no of symptoms (patients)	41 (37)	(15)	6

In total, 41 reports of allergic reactions/symptoms in 37 patients were considered to be related to the vaccination. Allergic reactions considered not related were reported in 6 patients.

Four of the five patients with anaphylactic reactions had a known allergy to certain foods or medicines. In all cases the reactions occurred within one hour after the vaccination. In two of the patients, hypotension was reported, and four patients reported dizziness, tingling, oedema of the lips and throat, and moderate difficulty breathing. None of the patients developed anaphylactic shock. All patients recovered after treatment with adrenaline, corticosteroids and antihistamines. Allergic reactions such as anaphylaxis, angioedema and urticaria are not specified in the product information for Pandemrix.

Two of the patients who were diagnosed with "allergic reaction" had previously known egg allergy. One of these patients had a strong reaction directly after the vaccination, but the symptoms were relieved quickly with adrenaline, cortisone and antihistamine treatment. The other patient had a transient urticarial reaction.

### Deaths reported

Five 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 days. These five patients had previously known chronic diseases such as cardiovascular disease, diabetes, renal failure, dystrophic muscle disease and senile dementia. All patients were on chronic medical treatment. Three of the patients were >74 years, the two others between 54 and 65. Autopsy result is available for the first reported case. This showed that the patient suffered from generalized atherosclerosis and previous heart attacks. The other reports are still under investigation and autopsy results are awaited. From what has emerged so far for these cases, there is nothing to support a causal association between the vaccination and the death.

In assessing the number of reported deaths, it is 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 began, the MPA has received more than 450 consumer reports. Still a large majority, about 90% of reports, describe non-severe, expected and known reactions. The potentially serious cases are similar to the ones previously reported (such as events of transient flu-like symptoms, severe pain at the injection site, pain in arm and adjacent muscles). Despite the fact that an adverse reaction is known and judged as non-serious, symptoms may of course still be perceived as troublesome to the individual. Some patients have reported that the reactions to this influenza vaccine differ from their experience with previous seasonal flu vaccinations, such as more pronounced pain in the injection arm and stronger flu-like symptoms.