

## Pharmacovigilance of A (H1N1) influenza vaccines

11 February 2010

In the following table the data on postmarketing experience published by six national regulatory agencies are summarised. For further information: [www.who-umc.org/DynPage.aspx?id=85898](http://www.who-umc.org/DynPage.aspx?id=85898)

The majority of reported adverse events were local reactions in the injection site and general symptoms of influenza (fever, chills, headache, myalgia, etc.).

### Please remember:

- Reports of adverse events in patients who have received the vaccine do not necessarily imply a causal role of the vaccine.
- Vaccines against influenza can also induce other adverse effects which may take a longer time to manifest (immune system disorders, cardiovascular disorders, etc).

### Additional information:

Remember that the vaccines in use in Spain are **contraindicated in individuals with egg allergy**, due to the risk of acute anaphylactic reaction.

On November 24 Infarmed, the Portuguese Agency of Medicines, informed about three cases of abortion in pregnant women, soon after they had been vaccinated with Pandemrix®. The causal relationship was judged unlikely. The Infarmed also quotes 8 additional reports of abortion in other European countries ([www.infarmed.pt](http://www.infarmed.pt)).

Please remember that the summary of product characteristics of **Panenza®** (a non adjuvated vaccine approved by the Spanish Agency of Medicines and Health Products but not by the EMEA, and recommended for pregnant women) states the following warnings:

- *A protecting immune response may not develop in all vaccinated persons.*
- *No data are available on the safety, immunogenicity or efficacy supporting interchangeability of Panenza® with other H1N1 pandemic vaccines.*
- *The immune response may be diminished in patients under immunosuppressive treatment.*
- *At present no data are available on the use of Panenza® during pregnancy.*
- *No data are available on the postmarketing safety of Panenza®.*

On December 4 the EMEA informed that young children may experience fever after their second dose of Pandemrix® ([www.emea.europa.eu](http://www.emea.europa.eu)).

### Antiviral drugs

In Butlletí Groc of April-June 2009 the efficacy and adverse effects of oseltamivir and zanamivir were summarised.

The data recently published by the US FDA confirm the risk of neuropsychiatric adverse effects of oseltamivir initially described in Japan, in particular in young patients.

	<b>Spain</b> <a href="http://www.aemps.es">www.aemps.es</a>	<b>France</b> <a href="http://www.afssaps.fr">www.afssaps.fr</a>	<b>United Kingdom</b> <a href="http://www.mhra.gov.uk">www.mhra.gov.uk</a>	<b>Sweden</b> <a href="http://www.lakemedelsverket.se">www.lakemedelsverket.se</a>	<b>Canada</b> <a href="http://www.hc-sc.gc.ca">www.hc-sc.gc.ca</a>	<b>USA</b> <a href="http://vaers.hhs.gov">http://vaers.hhs.gov</a>
Date of last report	15 Jan	4 Feb	4 Feb	18 Jan	3 Feb	28 Jan
Brand name	Pandemrix® <sup>a</sup> Focetria® <sup>b</sup> Panenza® <sup>c</sup>	Pandemrix® <sup>a</sup> Panenza® <sup>c</sup>	Pandemrix® <sup>a</sup> Celvapan® <sup>d</sup>	Pandemrix® <sup>a</sup>	Arepanrix® <sup>e</sup> Panvax® <sup>f</sup>	Five vaccines <sup>g</sup>
N° of administered doses	2,000,000	5,700,000	4,000,000	5,300,000	25,143,000	122,000,000
N° of reports	1.025	3,753 <sup>h</sup>	2,817	3,700 <sup>i</sup>	6,029	8,755
N° of adverse reactions	2,828	n.d. <sup>j</sup>	7,487	n.d. <sup>j</sup>	n.d. <sup>j</sup>	n.d. <sup>j</sup>
Most frequent adverse reactions	General and injection site	General and injection site	General and injection site	General and injection site	General and injection site	General and injection site
Severe (n)	n.d. <sup>j</sup>	194	n.d. <sup>j</sup>	n.d. <sup>j</sup>	245	564
Lethal outcome (n)	n.d. <sup>j</sup>	n.d. <sup>j</sup>	15	20	13	42
Relevants	GBS <sup>k</sup> (6), anaphylaxis (2), facial paralysis (4), convulsions (7), abortion (2), foetal death (1)	GBS <sup>k</sup> (5), anaphylactic shock (3), multiple sclerosis exacerbation (5), abortion (10), foetal death (12)	GBS <sup>k</sup> (7), convulsions (26), foetal death (3), abortion (16)	GBS <sup>k</sup> (5), facial paralysis (13), convulsions (24), foetal death (5), abortion (22)	GBS <sup>k</sup> (24), serious anaphylaxis (130)	GBS <sup>k</sup> (61)

**a** 3.75 µg of hemagglutinin, with adjuvant, virus grown in eggs.

**b** 7.5 µg of hemagglutinin, with adjuvant, virus grown in eggs.

**c** 15 µg d'hemagglutinina, no adjuvant, virus grown in eggs.

**d** 7.5 µg of hemagglutinin, no adjuvant, virus grown in cells, without traces of egg.

**e** 3.75 µg of hemagglutinin, with adjuvant, virus grown in eggs.

**f** 15 µg d'hemagglutinina, no adjuvant, virus grown in eggs.

**g** Four of inactivated virus and without any adjuvant, and one of attenuated live viruses administered by inhalation.

**h** 2,931 from health professionals plus 805 from users.

**i** Around 1,700 from health professionals, plus around 2,000 from users.

**j** No data available.

**k** Guillain-Barré syndrome.

**l** One in a patient with a history of egg allergy, the other in a patient with a history of allergy to dried fruits.