IRISH MEDICINES BOARD

Illustrative copy of the Irish Medicines Board Pandemic Adverse Reaction Online Reporting Form

As limited safety data on novel H1N1 influenza vaccines are currently available, additional pharmacovigilance activities are essential to monitor and assess their safety with widespread use. Due to the possible disruption of the postal system and limited time available to healthcare professionals, the IMB recommends that healthcare professionals should, where feasible report adverse reactions using the **on-line reporting system**, which is accessible via the pandemic flu webpage on the IMB homepage (**www.imb.ie**). This is available now and will continue to operate for the duration of the pandemic.

The form incorporates five brief sections, which are illustrated in this document. Fields marked with an asterisk (*****) are mandatory. To move through the steps of the form please use the **Next** and **Previous** buttons that are at the bottom of the each page of the form.

Please provide as much information as possible, and particularly:

- Vaccine trade name
- Batch number
- Dates of initial and second (if applicable) vaccination
- Date of onset of the reaction
- Treatment received
- Outcome of the reaction
- Relevant medical history
- Age and gender of the patient

Page 1 – Reporter Information

Title: *	Please Select
First Name: *	
Surname: *	
Organisation:	
Department:	
Address 1: *	
Address 2:	
Address 3:	
City:	
County:	Please Select
Country:	Ireland
Telephone:	
Mobile:	
Email: *	
Confirm Email: *	
Reporter Type:	Please Select
Other:	

Page 2 – Patient Information

Initials/Record No:

Gender: Please Select

Age (at time of event):

Weight:

Is the patient pregnant?: ○ N/A ○ No ○ Yes

If Yes?: ○ 1st Trimester ○ 2nd Trimester ○ 3rd Trimester ○ Unknown

Is the patient breastfeeding?: ○ N/A ○ No ○ Yes

Is the reaction in a baby who is being breastfed?: ○ N/A ○ No ○ Yes

Relevant Medical History/Underlying Conditions: (for example, Cystic fibrosis; asthma; HIV; COPD)

Page 3 – Suspect Drug(s) and Concomitant Medications

For reports associated with **suspected Swine Flu medication** please select the following:

Tamiflu (oseltamivir) 30mg ○ 45mg ○ 70mg ○ Suspension ○

Relenza Inhalation Powder (zanamivir) ○

H1N1 Swine Flu Vaccine (Baxter) ○

H1N1 Swine Flu Vaccine (GSK) ○

H1N1 Swine Flu Vaccine (Unknown Manufacturer) ○

Or please enter the name of the **suspect** product into the field provided:

Product/Trade Name: (as displayed on the Label/package)

Active Substance (if known):

Batch Number(s):

Indication for Use:
○ Prevention of flu
○ Treatment of flu

Injection Site(s):

Daily Dosage:

Dates of Treatment: From: / / To: / /

1st Vaccination Date: / / 2nd Vaccination Date: / /

Duration of Use:

Duration of Use before reaction:

Additional Information:

Page 3 – Suspect Drug(s) and Concomitant Medications (continued)

Were any other drug(s) used over this period? Please ensure that you include all medications (including herbals) or vaccines administered in the last 3 months:

Other drugs used?: ◯ Yes ◯ No

Please enter the Product/Trade Name or Active Substance (or both) *

Product/Trade Name: (as displayed on the Label/package)

Active Substance (if known):

Daily Dosage:

Indication for Use:

Dates of Treatment: From: / / To: / /

1st Vaccination Date: / / 2nd Vaccination Date: / /

If you wish to add more products please click here: **Add Product**

Additional Information:

Page 4 – Suspected Reaction(s)

Description of Reaction(s): *
-OR-

Lack of Efficacy: *
-OR-

Medication Error: *

Reaction Date: / /

Duration of Reaction:

Treatment given in response to the reaction:

Add

Additional Information

Enter any additional information you wish here:

Page 5 – Outcome

Recovery from side effects: * Please Select

Drug discontinued: Unknown

Manufacturer Notified: Unknown

If you are a carer/patient do you permit us to contact your doctor or any other healthcare professional to assist with the investigation of the case? ◯Yes ◯No

Name & Address of Healthcare Professional:

Additional Information

Enter any additional information you wish here:

Once you have completed these pages you will be given the opportunity to review all the information you have entered in a simple tabular format. If you are happy with the information, press the **Submit** button. The information will be automatically and instantaneously be submitted to the IMB, and you will be issued an online reporting reference number for your records.

For further information please visit the IMB website
www.imb.ie

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