Three deaths may have link to flu jab

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Exclusive

Three patient deaths have been reported to the State's drugs monitoring agency relating to administration of the swine flu vaccine Pandemrix in the past two years, according to figures obtained by **irishealth.com**

The deaths occurred in a baby whose mother was given the vaccine, and in two elderly people.

And the Irish Medicines Board (IMB) has told **irishhealth.com** that 139 deaths were linked to medicines in the top 10 list* (see below) that had the highest number of reported adverse reactions from January 2010 to December 2011.

The IMB has stressed that that three deaths reported to it in patients exposed to Pandemrix does not necessarily indicate a direct link between the vaccine and the deaths.

The Medicines Board says in many cases where patients' deaths were linked to drug or vaccine reactions, the death may have been caused by other factors, such as underlying illnesses or progression of the patients' disease, and many of the patients taking drugs where fatalities were reported were already seriously ill.

However, the Medicines Board cannot state for certain exactly how many of the deaths reported to it among those taking medicines may have been directly linked to a reaction to a particular drug/vaccine.

It says of those fatal reports received in relation to Pandemrix, two of the patients were aged over 80 years and were reported to have had pneumonia.

In the third case, the death reported was of a newborn infant.

Howwever, the IMB said the baby, whose mother had previously been given the Pandemrix vaccine, was seriously ill and had multiple post-birth complications. It said the infant's death was unlikely to have been a direct fatality as a result of an adverse reaction to the vaccine.

The deaths were recorded among 779 reports of adverse reactions to pandemic flu vaccines given to the IMB over the two-year period.

There have been reports of a possible link between Pandemrix and the sleeping disorder narcolepsy in young people.

The IMB said many people who received the H1N1 vaccines had chronic underlying medical conditions which put them at greater risk of developing serious complications.

"Some of these patients may naturally have suffered an exacerbation of their underlying illness, and such events may coincidentally occur around the time of vaccination and as such, be reported to the IMB. It is important to bear in mind that this temporal association does not in itself mean that the vaccine was responsible for the (adverse) event and the timing may be purely coincidental."

The IMB revealed to **irishhealth.com** that a total of 139 deaths were recorded among the 10 drugs with the most adverse reactions reported to it between the beginning of 2010 and the end of 2011. However, the IMB has said in many cases the deaths were not likely to have been directly related to taking the drug.

It said adverse reaction reports submitted to it in many cases arose from suspicions occurring during observation of an unexpected and/or unwanted medical event in the context of use of a medicine.

It said in many cases where patients are reported to have died, the patients had significant underlying illness and were treated with multiple medicines and/or surgery. Also, many of these cases were also affected by disease progression or other complications unrelated to the medicine.

The IMB added that where it stressed the need for greater monitoring of a drug, this resulted in increased reporting which could include include adverse event reports not directly related to the drug, but occurring during the time a patient was treated.

The adverse reaction reports are usually sent in to the IMB by health professionals, consumers and pharmaceutical companies.

This is the first time the IMB has released details of mortality figures reported with adverse drug reactions.

The drug associated with the greatest number of adverse reaction reports indicating a fatal outcome was the schizophrenia treatment clozapine, with 58 deaths reported for 2010 and 2011, among 543 adverse reactions in total.

The IMB said there were rigorous safety monitoring procedures in place for clozapine use. It said the drug can potentially cause a serious blood disorder, agranulocytosis, and for this reason there is a requirement for specific monitoring of blood levels while on the drug.

It said this level of monitoring resulted in sustained levels of adverse reaction reporting with the drug, but none of the deaths reported were related to the blood disorder.

The IMB stressed that in many cases patient mortality cannot be directly linked to taking a specific drug.

It said interpretation of reactions to medicines in cases where multiple other treatments have been used requires special care.

This was particularly relevant for vaccines, as many were administered in combination, making it difficult to establish whether a particular vaccine or medicine caused the unexpected or unwanted event in question.

There were no deaths reported from vaccines used in the child immunisation scheme or from the HPV(cervical cancer) vaccine.

***Adverse drug reactions (ADRs) and fatalities reported to IMB - January 2010–December 2011**

(ADRs/Deaths)

PANDEMIC INFLUENZA VACCINES: 779/3

CLOZAPINE: 543/58
HPV VACCINES: 507/0
VACCINES IN CHILD IMMUNISATION SCHEME: 379/0
ADALIMUMAB: 166/4
PALIVIZUMAB: 165/18
SORAFENIB: 92/22
DOCETAXEL: 81/2
DARBEPOETIN ALFA:80/31
VARENICLINE TARTRATE: 77/1

Total fatalities - 139.

Total Adverse drug reactions - 2,090

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