Drug Information Bulletin

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Content

Editorial

Recent interactive meeting between US FDA officials and representatives of Pharma associatio seems to be a relief for the Pharmaceutical manufacturers of India.

Since 2013 USFDA has served import alert to more than 30 Indian units for several violation Import alert would mean products manufactured at these sites will not be allowed to enter t United States and the firms will not be able to make any generic drug applications from these site As per the source a consistent problem that USFDA has been finding at almost all of the units that of data integrity, where USFDA has found instances of faking data, incomplete record retesting to match results.

In the above said meeting the officials of Indian Government and representative of the Pharmex have expressed that they are committed to quality of medicines manufactured in India and see cooperation from USFDA. The USFDA representatives also expressed their concern about the quali and expect complete compliance with cGMP and data integrity.

In an interactive session representatives of several associations including Indian Pharmaceutic Association placed questions and suggestions, which have been addressed by the USFD representatives cordially. Hope this is a good beginning to ease the strained situation and will b resolved soon with some more interactions.

With this editorial we are completing eighth year of journey, which are possible due to consta help, co operation and encouragement for our readers. We are expecting the same for the future.

I would like to thank you all for your kind inputs which made this shape and request you to sen your inputs through the enclosed feedback form for further improvement.

Dr. Subhash C. Mandal

Editor

New Drug: Influenza H1N1 vaccine

Aust Prescr 2009;32:165-171

Panvax H1N1 vaccine (CSL)
single dose vials containing 15 microgram of haemagglutinin in 0.5 mL and multi dose vials containing 5 mL or 10 mL vaccine
Approved indication: prevention of 2009 H1N1 influenza
Australian Medicines Handbook section 20.1

Following the rapid spread of a new influenza A H1N1 virus, also called swine flu, the World Health Organization (WHO) declared an influenza pandemic on 11 June 2009.1This prompted the development of a 2009 H1N1 vaccine.

Using the same methods employed to make the seasonal influenza vaccine2, a monovalent split-virus inactivated vaccine that does not have adjuvant has been developed. The virus, which was grown in embryonated chicken eggs, was prepared from the reassortant vaccine virus NYMC X-179A derived from the influenza A/California/7/2009 H1N1 virus (recommended by the WHO).

The safety and immunogenicity of two doses of the vaccine 15 microgram of haemagglutinin antigen in 0.25 mL and 30 microgram in 0.5 mL have been tested in 240 healthy adults (aged 18-64 years) in South Australia.3Half of the participants were aged 50 or over. Pregnant women were not included in the trial. Two injections of the vaccine were given three weeks apart, in the deltoid muscle of the upper arm. An interim analysis of patient sera found that most people in the trial had produced a robust antibody response three weeks after receiving the first dose (15 or 30 microgram). Neutralising antibody titres of 1:40 or more in a haemagglutination-inhibition assay were observed in 96.7% of people in the lower dose group and 93.3% in the higher dose group. (The haemagglutination-inhibition assay quantifies the highest dilution of patient sera that is able to block haemagglutination of red blood cells by H1N1 virus.) On average, 74.2% (66.1-82.3%) of participants had either seroconverted or had a significant increase in antibody titre. However, people aged 50 or over had a lower-fold increase in antibody response from baseline compared to younger participants.3

The fact that most people had high antibody titres after one vaccination was an unexpected result - it was anticipated that two doses of the vaccine would be needed as most people would not have had previous exposure to the H1N1 virus. However, at baseline it turned out that over a third of participants (76 of 240) already had antibody titres of 1:40 or more in the haemagglutination-inhibition assay, regardless of their age. This proportion was even higher in people who had received the 2009 seasonal influenza vaccine 44% of them (48 of 108) had antibody titres of 1:40 or more at baseline.

The most commonly reported adverse events in the trial were tenderness (30.8% of vaccinees), pain (20.8%) and induration (10%) at the injection site. Other common events included headache (25.8%), malaise (11.7%) and myalgia (15.8%). Three people reported influenza-like illness one of these tested positive for 2009 H1N1 influenza eight days after vaccination while the other two people tested negative. There were no withdrawals from the trial.3

The vaccine is indicated for adults, adolescents and children over 10 years of age and should be given by intramuscular or deep subcutaneous injection. However, it should not be given to people who have had a life-threatening reaction to influenza vaccination, or who have had Guillain-Barr syndrome within six weeks of a previous influenza vaccination. Likewise, it is contraindicated in people who have anaphylactic hypersensitivity to eggs, chicken protein or other constituents of the vaccine. Immune responses to the vaccine may be lower in immunocompromised patients. Immunisation should be postponed in people who have a febrile illness or acute infection.

Based on the interim analysis, it appears that a single 15 microgram dose of the vaccine is immunogenic in healthy adults. However, around a third of people in the trial already had H1N1-specific antibodies before they were vaccinated.3 The actual effectiveness of the vaccine to protect against influenza A H1N1 virus will not be known until after a mass immunisation program has taken place. Vulnerable groups of patients such as pregnant women, children, the elderly and people with impaired immunity were not included in the trial so it is not known how the vaccine will perform in these individuals.

References

1. World Health Organization. Director-General statement following the meeting of the Emergency Committee. 2009 Jun 11. www.who.int/csr/disease/swineflu/4th_meeting_ihr/en/index.html[cited 2009 Sep 29]
2. Talbot HK, Keitel W, Cate TR, Treanor J, Campbell J, Brady RC, et al. Immunogenicity, safety and consistency of new trivalent inactivated influenza vaccine. Vaccine 2008;26:4057-61.
3. Greenberg ME, Lai MH, Hartel GF, Wichems CH, Gittleson C, Bennet J, et al. Response after one dose of a monovalent influenza A (H1N2) 2009 vaccine - preliminary report. N Engl J Med 2009;361:1-10.

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NPPA directs pharma companies to pass on lower excise duty benefit

Medicine prices are set to become cheaper with drug pricing regulator NPPA directing drug makers to pass on benefits of lower excise duty to consumers.
The government has exempted drugs and pharmaceuticals from the the levy of Education Cess and Secondary and Higher Education Cess, resulting into reduction of excise duty from 6.18% to 6%, National Pharmaceutical Pricing Authority (NPPA) said in notification.

In exercise of the powers conferred on it by Drugs (Prices Control) Order, 2013, the NPPA "directs all the manufacturers to ensure to revise their Maximum Retail price (MRP), inclusive of excise duty and all taxes, of all formulation packs downward, pursuant to aforesaid notifications dated March 1, 2015," it added.

The above reduction in the MRP shall take effect immediately, NPPA said.

"However, where no excise duty has been actually paid/ payable to the government and no excise duty is chargeable in the MRP of such formulation packs, the reduction in prices of those formulation packs may not apply to the categories of concerned formulation packs," it added.

Established in 1997, NPPA has been

entrusted with the task of fixation/revision of prices of pharmaceutical products (bulk drugs and formulations), enforcement of provisions of the Drugs (Prices Control) Order and monitoring of the prices of controlled and decontrolled drugs in the country.

WHO warns Ebola-affected countries about disease outbreaks

The World Health Organization has called for mass immunizations to counter the increasing risk of outbreaks of other diseases, such as whooping cough and measles, in West African countries fighting the Ebola epidemic. A warning note was released by the WHO on Friday to inform the public that disruption in vaccination services caused by the Ebola epidemic could increase the possibility of outbreaks of vaccine-preventable conditions in those countries. The WHO also confirmed that mass measles vaccination campaigns will be launched in as many countries as possible.
Reference: Reuters

ASCI upholds complaints against 151 out of 201 advertisements

In January 2015, ASCI's Consumer Complaints Council (CCC) upheld complaints against 151 out of 201 advertisements. Out of 151 advertisements against which complaints were upheld, 90 belonged to Personal and Healthcare category, followed by the Education category with 40 advertisements.

Health and Personal Care:

The CCC found the following claims in health and personal care product or service advertisements of 90 advertisers to be either misleading or false or not adequately/scientifically substantiated and hence violating ASCI's Code. Some of the health care products or services advertisements also contravened provisions of the Drug & Magic Remedies Act and Chapter 1.1 and III.4 of the ASCI Code. Complaints against 90 advertisements were **UPHELD**. Details are available at: http://www.exchange4media.com/59491_asci-upholds-complaints-against-151-out-of-201-advertisements.html

Forthcoming Events