

In a first, WHO recommends quadrivalent influenza vaccine

Sanofi Pasteur's injectable influenza vaccine for active immunisation of adults 18 to 64 years of age was approved in May last year by DCGI.

Sanofi Pasteur's injectable influenza vaccine (FluQuadri) containing two A virus strains — H1N1 and H3N2 — and two B virus strains — Victoria and Yamagata — for active immunisation of adults of age 18 to 64 years was approved in May last year by the Drug Controller General of India (DCGI). The application for the paediatric indication is under review by the DCGI and final approval is expected by the end of this month.

Sanofi's quadrivalent influenza vaccine was licensed for use by the U.S. Food and Drug Administration (FDA) in 2013; it is licensed in 26 countries.

Better protection

While a trivalent influenza vaccine contains both A subtype viruses, it has only one of the B subtype virus, the quadrivalent vaccine offers greater breadth of protection as it includes both B subtype viruses. It is because of greater breadth of protection that a few other companies too have shifted from a trivalent to a quadrivalent vaccine.

Since the vast majority of influenza vaccines manufactured were trivalent till recently, the World Health Organisation (WHO) used to recommend two A subtypes and one B subtype, plus an optional fourth strain (the other B virus strain). But this February 2018, for the first time, the WHO issued an official recommendation for a quadrivalent vaccine. "It is recommended that quadrivalent vaccines for use in the 2018-2019 northern hemisphere influenza season," the WHO noted.

The quadrivalent vaccine will contain four influenza virus strains (two A subtypes and two B subtypes — H1N1 and H3N2, and Victoria and Yamagata respectively). The WHO recommendation then mentioned which B strain should be removed in the case of a trivalent flu vaccine.

The viruses used in the vaccine are killed and this eliminates the possibility of the virus in the vaccine itself causing infection. In India, the vaccine will be available as single dose pre-filled syringe. Eventually, it will be available in a vial for public health use. In the case of H1N1, there are two strains — California and Michigan — that cause influenza. In India, the Michigan strain was earlier circulating and has been replaced by the California strain. For 2018, the WHO has recommended the Michigan strain for the southern hemisphere, including India.

Each year, the vaccine changes to reflect the different strains in circulation. Year round, scientists across the globe track, analyse and classify the viral strains causing illness. This allows the WHO to select the strains in February for the upcoming season's vaccine.

Since 2011, there have been about 97,000 H1N1 cases and over 7,100 deaths in India according to the Integrated Disease Surveillance Project (IDSP) data. Till June 3 this year, there have been 1,740 seasonal influenza cases and 191 deaths caused by H1N1. The years 2015 and 2017 witnessed a sharp increase in the number of cases and deaths. There were 42,592 and 38,811 cases and 2,990 and 2,270 deaths in 2015 and 2017, respectively.

Indian context

Despite the high number of infections and mortality each year, India does not have in place a

national policy for influenza immunisation. Pregnant mothers, children aged below five and young people with asthma, cardiovascular disease, diabetes and high blood pressure are at a greater risk of infection and death. The Ministry of Health issues only H1N1 vaccination guidelines for different vulnerable groups including healthcare workers.

“If you want to reduce the influenza burden in adults, then we must target children as they act as reservoirs,” Dr. Su-Peing Ng, Sanofi Pasteur, Head of Global Medical Affairs.

“Influenza can be seasonal or pandemic. What we observed during the 2009 pandemic is that countries which traditionally had good seasonal vaccine coverage could reach 50% coverage during the pandemic. Other countries achieved only 20% vaccination coverage during the pandemic. So seasonal vaccination is part of pandemic preparedness,” said Dr. Pier Luigi Lopalco, Professor of Hygiene and Preventive Medicine at the University of Pisa, Italy.

“When people can use the seat belt each time they drive why not get vaccinated against influenza just once a year?” asked Dr. Su-Peing.

(The Correspondent visited Sanofi Pasteur’s vaccine manufacturing unit at Val de Reuil near Paris at the invitation of Sanofi Pasteur)

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