

10 August 2010

Proposals for influenza vaccine

PHARMAC is seeking feedback on a proposal to list two brands of influenza vaccine in the Pharmaceutical Schedule for the 2011, 2012, and 2013 influenza seasons. In summary, this proposal would result in:

- Fluvax and Fluarix being listed in the Pharmaceutical Schedule from 1 January 2011 under the eligibility criteria specified by the Ministry of Health.
- 250,000 doses of Fluarix would be distributed in preference to Fluvax, after which supplies of Fluvax would be expected to meet the demand of the market.
- Distribution mechanisms would be largely as they are now, however the Ministry of Health would be permitted to place some stock on reserve for specific patient groups if it considered targeting was desirable.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Wednesday, 25 August 2010** to:

Andrew Davies	Email: andrew.davies@pharmac.govt.nz
Procurement Initiatives Manager	
PHARMAC	Fax: 04 460 4995
PO Box 10 254	
Wellington 6143	

All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

PHARMAC has entered into two provisional agreements, one with CSL Biotherapies Limited (CSL) relating to Fluvax, and one with GlaxoSmithKline New Zealand Limited (GSK) relating to Flurix.

If approved, the proposal would result in the following brands of Influenza vaccine being listed on the Pharmaceutical Schedule from 1 January 2011:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Influenza Vaccine	Pre-filled syringe, 0.5 ml	Fluarix	10	\$90.00
Influenza Vaccine	Pre-filled syringe, 0.5 ml	Fluvax	10	\$90.00

Both vaccines would contain the antigens specified by the World Health Organisation for the relevant Southern Hemisphere influenza season.

Both brands of influenza vaccine would be subject to a confidential rebate arrangement for eligible patients, and for vaccine directly purchased by DHB Hospitals.

Influenza vaccine would be subsidised by the Ministry of Health for eligible patients and for a period of time as specified by the Ministry of Health. Currently the following patients are Eligible¹:

- a. all people 65 years of age and over;
- b. people under 65 years of age with:
 - i. the following cardiovascular disease:
 1. ischaemic heart disease,
 2. congestive heart disease,
 3. rheumatic heart disease,
 4. congenital heart disease, or
 5. cerebo-vascular disease;
 - ii. the following chronic respiratory disease:
 1. asthma, if on a regular preventative therapy, or
 2. other chronic respiratory disease with impaired lung function;
 - iii. diabetes;
 - iv. chronic renal disease;
 - v. any cancer, excluding basal and squamous skin cancers if not invasive;
 - vi. the following other conditions:
 - A. autoimmune disease,
 - B. immune suppression,
 - C. HIV,
 - D. transplant recipients,
 - E. neuromuscular and CNS diseases,
 - F. haemoglobinopathies, or
 - G. children on long term aspirin.
- c. people under 65 years of age who are:
 - i. pregnant; or
 - ii. morbidly obese
- d. children aged over 6 months and under 5 years who are from high deprivation backgrounds

The following conditions are excluded from funding:

- e. asthma not requiring regular preventative therapy,
- f. hypertension and/or dyslipidaemia without evidence of end-organ disease.

Influenza vaccine would be distributed much in the same way as it has been in previous years. The Fluarix stock would be given supply preference at the beginning of the season until 250,000 doses had been distributed, after which the Fluvax stock would be distributed.

The provisional agreements permit the Ministry of Health to request that part of either supplier's stock is held in reserve, and distributed only for orders intended for particular patient groups.

CSL would liaise with the National Influenza Strategy Group (NISG) with respect to promotional activities related to influenza vaccine.

¹ Some of these groups were added as part of the influenza pandemic response, and may not be included in 2011. The Ministry of Health is in the process of reviewing the current criteria.

Background

In April 2010, PHARMAC released a request for proposals for influenza vaccine seeking agreements with two suppliers. We have assessed the proposals received, and have entered provisional agreements with CSL and GSK as detailed above.

Influenza vaccination for under 5s

Influenza vaccination is commonly associated with fever in the 24-48 hours following vaccination, particularly in younger age groups. During the assessment of the proposals, we examined reports that in the 2010 season Fluvax had been associated with higher rates of fever in the under 5 age group than other brands of vaccine, observed following reports of febrile convulsions in Western Australia.

While it is not clear what has triggered the observations of higher rates of fever, we consider it would be appropriate to reserve part of the Fluarix stock for use in under 5s while the issue is examined further by regulatory authorities. At this stage it would be our intention to do so for the 2011 season.

We note that influenza vaccines are reformulated from year to year, and that given there is currently no indication of why Fluvax has been associated with a higher rate of fever in under 5s in the 2010 season, there may be a need to for greater awareness of how to detect and manage fever for parents of children under 5 who are vaccinated against influenza regardless of brand.