CONSULTATION

PHARMAC
Pharmaceutical Management Agency

20 August 2013

Proposals for influenza vaccine

PHARMAC is seeking feedback on a proposal to list two brands of influenza vaccine in the Pharmaceutical Schedule for the 2014, 2015, and 2016 influenza seasons. In summary, this proposal would result in:

- Influvac, Influvac Junior and Fluarix being listed in Section H and Section I of the Pharmaceutical Schedule from 1 January 2014 under the eligibility criteria set by PHARMAC.
- 250,000 doses of Fluarix would be distributed each season in preference to Influvac and Influvac Junior, after which supplies of Influvac and Influvac Junior would be expected to meet the remaining demand of the market.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **4 pm, Tuesday, 3 September 2013** to:

Greg Williams
Senior Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: greg.williams@pharmac.govt.nz
Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Details of the proposal

Provisional agreement

PHARMAC has entered into two provisional agreements, one with Abbott Laboratories (NZ) Limited (Abbott) relating to Influvac and Influvac Junior, and one with GlaxoSmithKline New Zealand Limited (GSK) relating to Fluarix.

If approved, the proposal would result in the following brands of Influenza vaccine being listed on the Pharmaceutical Schedule from 1 January 2014:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Influenza vaccine	Inj 45 mcg in 0.5 ml syringe	Fluarix	10	$90.00
Influenza vaccine	Inj 45 mcg in 0.5 ml syringe	Influvac	10	$90.00
Influenza vaccine	Inj 45 mcg in 0.5 ml syringe	Influvac	1	$9.00
Influenza vaccine	Inj 22.5 mcg in 0.25 ml syringe	Influvac Junior	1	$9.00

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

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

Eligibility criteria

Influenza vaccine would be subsidised for eligible patients for the period of the funded influenza season each year. The exact start and end dates for each season will be notified each year. Currently the following patients are Eligible (the eligibility criteria may change in the future):

A) is available each year for patients who meet the following criteria, as set by PHARMAC:
- a) all people 65 years of age and over;
- b) people under 65 years of age who
  - i) have 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) have the following chronic respiratory disease:
    - 1) asthma, if on a regular preventative therapy, or
    - 2) other chronic respiratory disease with impaired lung function;
  - iii) have diabetes;
  - iv) have chronic renal disease;
  - v) have any cancer, excluding basal and squamous skin cancers if not invasive;
  - vi) have any of the following other conditions:

a) autoimmune disease,
b) immune suppression,
c) HIV,
d) transplant recipients,
e) neuromuscular and CNS diseases,
f) haemoglobinopathies, or
g) are children on long term aspirin, or

vii) are pregnant.

c) people under 18 years of age living within the boundaries of the Canterbury District Health Board, or

d) are children ages four and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness.

Unless meeting the criteria above, the following conditions are excluded from funding:

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

B) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

C) Individual DHBs may fund patients over and above the above criteria. The claiming process for these additional patients should be determined between the DHB and Contractor.

D) Stock of the seasonal influenza vaccine is typically available from February until late July with suppliers being required to ensure supply until at least 30 June. Exact start and end dates for each season will be notified each year.

Needle length

The Influvac and Influvac Junior brand of influenza vaccine is presented in a pre-filled syringe with a 25 mm needle length, while the majority of influenza vaccines previously supplied to the New Zealand market have come with a shorter needle length (16 mm). The Centers for Disease Control and Prevention, Ministry of Health New Zealand and the World Health Organisation support the longer needle length for effective intramuscular delivery and reduced reactogenecity. [1,2,3]

PHARMAC has sought advice from members of the Immunisation Subcommittee as to the suitability of the 25 mm needle and it was considered acceptable. The Immunisation handbook provides advice on the process for safe immunisation[4]. We note that it is proposed that the Fluarix brand would continue to be supplied in a pre-filled syringe with a 16 mm needle length.

[1] Centers for Disease Control and Prevention (CDC). Administering Vaccines: Dose, Route, Site, and Needle Size. 2009. http://www.immunize.org/catg.d/p3085.pdf Accessed 13 August 2013;

[2] Ministry of Health. 2011. *Immunisation Handbook 2011* (pp. 59-65). Wellington: Ministry of Health.

[3] World Health Organization (WHO). Module 6: Holding an immunization session. In: Immunization in Practice: A practical resource guide for Health workers. 2004 Update. 2004. http://whqlibdoc.who.int/publications/2004/9241546514_(Module6).pdf Accessed 13 August 2013

[4] Ministry of Health. 2011. *Immunisation Handbook 2011* (pp. 59-65). Wellington: Ministry of Health.

Distribution and promotional activities

Influenza vaccines 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 each season until 250,000 doses had been distributed, after which the Influvac and Influvac Junior stock would be distributed.

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

Background

In April 2013, 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 Abbott and GSK as detailed above.