2015 seasonal influenza vaccines

Health professionals are advised that the 2015 seasonal influenza vaccines will contain two new strains of the virus, compared to the 2014 vaccines used in Australia and the 2014-15 vaccines used in the Northern Hemisphere. In addition, 2015 is the first time that quadrivalent influenza vaccines will be available in Australia alongside the trivalent options.

The double strain change has resulted in manufacturing delays due to the time it takes to develop, test and distribute the vaccines. This has set back the commencement of this year’s National Seasonal Influenza Immunisation Program to 20 April 2015, to ensure sufficient supplies of trivalent vaccine are available to meet the expected demand.

The delay will not affect vaccine supply volumes and no shortages are anticipated. Vaccines are also currently available outside the program through private prescription.

2015 strains

Following advice from the Australian Influenza Vaccine Committee, the TGA adopted the September 2014 World Health Organization recommendations for the strains to be covered for the 2015 season.

The trivalent vaccines include two influenza A strains and one B strain.

One of the A strains is the A/California/7/2009 (H1N1)-like virus, which has been in the seasonal vaccine since 2010.

The other two strains, including an A/Switzerland/9715293/2013 (H3N2)-like virus and a B/Phuket/3073/2013-like virus, are different to previous vaccines.

The quadrivalent vaccines contain the same strains as the trivalent options with the addition of a second B strain – a B/Brisbane/60/2008-like virus.

Further information on the strains is available on the TGA website.

Registered vaccines

For the 2015 influenza season, the TGA has registered nine vaccines.

See Table 1 and Table 2 for details of these vaccines and the age groups for which they are approved.

For further information on individual vaccines, please refer to the relevant Product Information (PI) documents.

Table 1. Registered quadrivalent seasonal influenza vaccines for 2015

<table>
<thead>
<tr>
<th>SPONSOR</th>
<th>TRADE NAME</th>
<th>AGE GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlaxoSmithKline</td>
<td>Fluarix Tetra</td>
<td>3 years and over</td>
</tr>
<tr>
<td>Sanofi-Pasteur</td>
<td>FluQuadri Junior</td>
<td>6-35 months</td>
</tr>
<tr>
<td></td>
<td>FluQuadri</td>
<td>3 years and over</td>
</tr>
</tbody>
</table>
Table 2. Registered trivalent seasonal influenza vaccines for 2015

<table>
<thead>
<tr>
<th>SPONSOR</th>
<th>TRADE NAME</th>
<th>AGE GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>BGP Products*</td>
<td>Influvac*</td>
<td>6 months and over</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>Fluarix*</td>
<td>6 months and over</td>
</tr>
<tr>
<td>Novartis Vaccines and Diagnostics</td>
<td>Agrippal*</td>
<td>6 months and over</td>
</tr>
<tr>
<td>Sanofi-Pasteur</td>
<td>Vaxigrip Junior</td>
<td>6-35 months</td>
</tr>
<tr>
<td></td>
<td>Vaxigrip*</td>
<td>6 months and over</td>
</tr>
<tr>
<td>bioCSL</td>
<td>Fluvax**</td>
<td>5 years and over **</td>
</tr>
</tbody>
</table>

# Previously the pharmaceutical division of Abbott Australasia.

* Guidance for the dose in children aged 6–35 months is available in the Product Information.

** Febrile events have been observed in children aged 5 to under 9 years after immunisation with bioCSL Fluvax. Therefore, in this age group, a decision to vaccinate with the 2015 bioCSL Fluvax vaccine should be based on careful consideration of potential benefits and risks in the individual.

bioCSL Fluvax – not for children under 5 years

Health professionals are reminded that bioCSL Fluvax is registered for use in children from the age of 5 years and must not be used in children under 5 years of age due to an increased risk of fever and febrile convulsions.

Additionally, bioCSL Fluvax should only be used in children aged 5 to under 9 years based on careful consideration of potential benefits and risks in the individual child.

This information is reinforced in the black box warning (Figure 1.) in the PI and supported by a warning that appears on all sides of the vaccine’s packaging (Figure 2.) and feature on an updated vaccine refrigerator sticker (Figure 3.) that will be distributed by bioCSL for the 2015 influenza season.

The TGA also advises health professionals to avoid using ‘Fluvax’ as a generic term for influenza vaccine to minimise the potential for confusion.

Figure 1. Black box warning in bioCSL Fluvax Product Information

WARNING: This season’s vaccine is indicated for use only in persons aged 5 years and over. It must not be used in children under 5 years (see Contraindications). It should only be used in children aged 5 to under 9 years based on careful consideration of potential risks and benefits in the individual (see Precautions).

Figure 2. Warning to appear on all sides of the bioCSL Fluvax packaging

DO NOT USE IN CHILDREN UNDER 5 YEARS

Reporting adverse events following influenza vaccine

In conjunction with the Office of Health Protection and state and territory health authorities, the TGA will be closely monitoring adverse event reports during the 2015 influenza vaccination program.

Health professionals are encouraged to report all adverse events associated with influenza vaccination in patients of any age to the TGA or through the current arrangements in their state or territory.

A new National Adverse Events Following Immunisation reporting form is now available on the TGA website as a reporting option.

Figure 3. The updated vaccine refrigerator warning sticker, which will be distributed by bioCSL for the 2015 influenza season

Please contact CSL Medical Information department on 1800 642 865 for any queries.

bioCSL (Australia) Pty Ltd. ABN 61 121 396 617. 63 Peppar Road, Derrimut, VIC 3026, Australia. FLUVAX is a registered trademark of CSL Limited. Date of preparation: November 2014. FWA/914/0031. 12/03.
Agomelatine (Valdoxan) – monitoring of liver function

Health professionals are advised that the Product Information for agomelatine 25 mg, marketed in Australia as Valdoxan, has been updated to include further information about the risk of hepatic injury.

Agomelatine is a melatonin receptor (MT1 and MT2) agonist and 5-hydroxytryptamine (serotonin) receptor 2C antagonist. It is indicated for treatment of major depression in adults, including prevention of relapse. The most recent update to the Product Information (PI) clarifies and expands on changes made in December 2013. It includes additional information in the precautions and dosage and administration sections regarding monitoring of liver function. The updated PI advises caution before initiation of treatment with agomelatine and close surveillance of liver function during continuing treatment. This is especially important if agomelatine is used in combination with other medicines associated with risk of hepatic injury or where risk factors for hepatic injury, such as overweight/obesity, non-alcoholic fatty liver disease, diabetes and substantial alcohol consumption, are present.

It is also recommended that liver function tests be performed in all patients before initiation of treatment and before increasing the dose. Treatment should not be initiated if serum transaminase levels are greater than three times the upper limit of the normal range. Caution should be exercised if agomelatine is used in patients with pre-treatment transaminase levels greater than the upper limit of the normal range (but less than three times the upper limit).

Liver function tests should be performed around three weeks, six weeks, 12 weeks and 24 weeks after commencing treatment, and thereafter when clinically indicated. When increasing the dosage of agomelatine, liver function tests should be performed again at the same frequency as above.

Non-steroidal anti-inflammatory drugs and diclofenac reviews

Health professionals are advised that Product Information and labelling changes will be undertaken for the non-steroidal anti-inflammatory drugs diclofenac, naproxen, ibuprofen, celecoxib, etoricoxib, indomethacin, meloxicam and piroxicam. These changes follow a review of the cardiovascular risks associated with the use of these medicines and full safety review of diclofenac.

All eight non-steroidal anti-inflammatory drugs (NSAIDs) reviewed by the TGA are available as prescription medicines, while diclofenac, naproxen and ibuprofen are also available in lower dose over-the-counter (OTC) oral forms. Diclofenac, ibuprofen and piroxicam is also available as OTC topical gels.

Background

The NSAIDs review considered approximately 200 relevant papers published since 2005, as well as information supplied by the sponsors of the eight medicines, adverse event report data collected by the TGA and expert advice obtained from the Advisory Committee on the Safety of Medicines. In addition to this, the full safety review of diclofenac evaluated approximately 250 articles, comprising a mixture of randomised trials, observational studies, systematic reviews and non-systematic narrative reviews.

The TGA advised health professionals that the Product Information for prescription-only diclofenac had been updated with further information about the increased risk of arteriothrombotic events in the August 2014 issue of Medicines Safety Update.

Summary of findings

While use of NSAIDs at prescription-only dosages was already known to increase the risk of high blood pressure, heart failure, myocardial infarction and
stroke, the TGA NSAIDs review found that these risks also applied to oral diclofenac, naproxen and ibuprofen available OTC.

Similarly, the risk of hepatotoxicity in relation to use of prescription diclofenac was known, but the diclofenac safety review found that oral products available OTC also carried this risk.

The reviews found that use of OTC NSAIDs was safe when they were used according to the recommended doses for short durations, as instructed on the label. However, inappropriate use or overuse of these medicines could pose a significant risk of cardiovascular events and, in the case of diclofenac, hepatotoxicity.

It was determined that the product labelling for OTC diclofenac, naproxen and ibuprofen did not carry strong enough warnings regarding these risks for all patients or adequate advice that people with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

The TGA has undertaken consultation regarding proposed additional warnings to be included in the Required Advisory Statements for Medicine Labels for OTC oral doses and is now considering the submissions received.

The TGA encourages the reporting of all suspected adverse reactions to medicines, including vaccines, over-the-counter medicines, and herbal, traditional or alternative remedies. We particularly request reports of:

- all suspected reactions to new medicines
- all suspected medicines interactions
- suspected reactions causing death, admission to hospital or prolongation of hospitalisation, increased investigations or treatment, or birth defects.

Reports may be submitted:

- using the ‘blue card’ available from the TGA website
- online at www.tga.gov.au
- by fax to 02 6232 8392
- by email to ADR.Reports@tga.gov.au

For more information about reporting, visit www.tga.gov.au or contact the TGA’s Post-market Surveillance Branch on 1800 044 114.

For the latest safety information from the TGA, subscribe to the TGA Safety Information email list via the TGA website.

For correspondence or further information about Medicines Safety Update, contact the Post-market Surveillance Branch at ADR.Reports@tga.gov.au or 1800 044 114.

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