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### Changed immunisation schedule from 1 March 2008

Due to a manufacturing problem in the USA, CSL/Merck have advised that **Comvax®** and **Pedvax®** vaccines will be out of stock from March until late 2008. Comvax® is a combination of *Haemophilus influenzae* type b (Hib) and hepatitis B vaccine. Pedvax® is *Haemophilus influenzae* type b vaccine (mainly given to children less than five years of age who have either never received a Hib containing vaccine or have an incomplete Hib schedule).

**Victoria will change the childhood immunisation schedule from 1 March 2008 for all babies and children due for their 2, 4, and 6 month old vaccines. As Comvax stock ends the 12 month old schedule will also be altered.**

<table>
<thead>
<tr>
<th>Age of child</th>
<th>Vaccines required</th>
<th>Comvax® available</th>
<th>Comvax® stock ended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth</td>
<td>HB VaxII Paediatric®</td>
<td></td>
<td>HB VaxII Paediatric®</td>
</tr>
<tr>
<td>2 months</td>
<td>RotaTeq®, Infanrix hexa®, Prevenar®</td>
<td>RotaTeq®, Infanrix IPV®, Prevenar®, Comvax®</td>
<td></td>
</tr>
<tr>
<td>4 months</td>
<td>RotaTeq®, Infanrix hexa®, Prevenar®</td>
<td>RotaTeq®, Infanrix IPV®, Prevenar®, Comvax®</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>RotaTeq®, Infanrix hexa®, Prevenar®</td>
<td>RotaTeq®, Infanrix IPV®, Prevenar®</td>
<td></td>
</tr>
<tr>
<td>18 months</td>
<td>Varilrix®</td>
<td>Varilrix®</td>
<td>Varilrix®</td>
</tr>
<tr>
<td>4 years</td>
<td>Priorix®, Infanrix IPV®</td>
<td>Priorix®, Infanrix IPV®</td>
<td>Priorix®, Infanrix IPV®</td>
</tr>
</tbody>
</table>
The when, who, what, how and where of the schedule changes

When are the schedule changes?
- The changes commence from 1 March 2008

Who is affected by the schedule changes?
- Babies due for their two, four and six month old (the primary schedule) vaccines
- Babies who have started the primary schedule with Infanrix IPV and require either the four and/or six month old doses
- Babies due for their 12 month old schedule of vaccines who had Infanrix hexa as all or part of the primary schedule
- Children less than five years of age needing catch-up doses of the two, four and six month old vaccines in the primary schedule.

What are the schedule changes?
- Infanrix-IPV is replaced by Infanrix hexa (diphtheria, tetanus, pertussis, polio, hepatitis B and Hib) for the primary schedule
- Babies who had Infanrix hexa as all or part of the primary schedule and are due for their 12 month old vaccines will be given Hiberix (Hib)
- Only use Comvax (until stock ends) at the 12 month old schedule point for those who received Infanrix-IPV at two, four and six months and Comvax at two and four months
- When there is no Comvax left for babies at 12 months of age - give babies, who have only received Infanrix-IPV at two, four and six months and Comvax at two and four months, separate doses of Hiberix vaccine and HB VaxII Paediatric (hepatitis B paediatric) vaccine
- Overdue children aged 15 months to less than five years, a primary schedule - give the first dose as Infanrix hexa and subsequent doses as Infanrix IPV plus HB VaxII Paediatric.

How do the changes affect the schedule?
- Infanrix-IPV (diphtheria, tetanus, pertussis and inactivated polio) is replaced by Infanrix hexa (diphtheria, tetanus, pertussis, hepatitis B, inactivated polio and Hib) therefore two extra antigens (hepatitis B and Hib) are combined into one vaccine given in the primary schedule
- One less injection is given in the primary schedule at two and four months
- Infanrix hexa given as dose three (due at six months ) in the primary schedule provides the final dose of hepatitis B antigen to complete the hepatitis B course
- Babies who have had Infanrix hexa at six months and are due for their 12 month old vaccines - give Hiberix (dose four of Hib antigen)
- When Comvax supply has ceased - give babies at the 12 month schedule, who had Infanrix IPV for the primary schedule, separate doses of Hiberix and HB VaxII Paediatric as well as Priorix and NeisVac C
- Overdue children aged 15 months to less than five years of age, commencing a primary schedule - give Infanrix hexa as the first dose. This age group only require a single dose of the Hib antigen. The primary schedule is completed with two further doses of Infanrix IPV and HB VaxII Paediatric vaccine as per the recommended catch-up schedule.

Where is the schedule unchanged?
- Varilrix is unchanged at 18 months of age
- Infanrix-IPV is unchanged at four years of age.
### Tables indicating transition from Infanrix IPV to Infanrix *hexa* in the primary schedule

#### Table 1. Where one dose of Infanrix *hexa* has been administered

<table>
<thead>
<tr>
<th>Age of child</th>
<th>Brand</th>
<th>Time given</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months</td>
<td>Infanrix IPV RotaTeq Comvax Prevenar</td>
<td>Vaccines given before March 2008</td>
</tr>
<tr>
<td>4 months</td>
<td>Infanrix IPV RotaTeq Comvax Prevenar</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>Infanrix <em>hexa</em> RotaTeq Prevenar</td>
<td>Vaccines given from March 2008</td>
</tr>
<tr>
<td>12 months</td>
<td>Hiberix Priorix NeisVac C</td>
<td></td>
</tr>
<tr>
<td>18 months</td>
<td>Varilrix</td>
<td></td>
</tr>
<tr>
<td>4 years</td>
<td>Infanrix IPV Priorix</td>
<td></td>
</tr>
</tbody>
</table>

#### Table 2. Where two doses of Infanrix *hexa* have been administered

<table>
<thead>
<tr>
<th>Age of child</th>
<th>Brand</th>
<th>Time given</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months</td>
<td>Infanrix IPV RotaTeq Comvax Prevenar</td>
<td>Vaccines given before March 2008</td>
</tr>
<tr>
<td>4 months</td>
<td>Infanrix <em>hexa</em> RotaTeq Prevenar</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>Infanrix <em>hexa</em> RotaTeq Prevenar</td>
<td>Vaccines given from March 2008</td>
</tr>
<tr>
<td>12 months</td>
<td>Hiberix Priorix NeisVac C</td>
<td></td>
</tr>
<tr>
<td>18 months</td>
<td>Varilrix</td>
<td></td>
</tr>
<tr>
<td>4 years</td>
<td>Infanrix IPV Priorix</td>
<td></td>
</tr>
</tbody>
</table>

#### Table 3. Where three doses of Infanrix *hexa* have been administered

<table>
<thead>
<tr>
<th>Age of child</th>
<th>Brand</th>
<th>Time given</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months</td>
<td>Infanrix <em>hexa</em> RotaTeq Prevenar</td>
<td>Vaccines given from March 2008</td>
</tr>
<tr>
<td>4 months</td>
<td>Infanrix <em>hexa</em> RotaTeq Prevenar</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>Infanrix <em>hexa</em> RotaTeq Prevenar</td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>Hiberix Priorix NeisVac C</td>
<td></td>
</tr>
<tr>
<td>18 months</td>
<td>Varilrix</td>
<td></td>
</tr>
<tr>
<td>4 years</td>
<td>Infanrix IPV Priorix</td>
<td></td>
</tr>
</tbody>
</table>

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**Infanrix *hexa* vaccine must be reconstituted by adding the entire contents of the syringe to the vial and shaking until the pellet is completely dissolved.**

**Hiberix vaccine must be reconstituted by adding the entire contents of the syringe to the vial and shaking until the pellet is completely dissolved.**
Scenarios for 1 March 2008 schedule change

Scenario 1
Baby Hamish, is born on 1st January 2008, he is brought to clinic by his mother on 1st March 2008 for his first vaccinations. You calculate he has just turned eight weeks of age.

- Administer dose one of each of the three due vaccines, Infanrix hexa, Prevenar and RotaTeq.
- Hamish is due for dose two of each vaccine in two months time.

Scenario 2
Baby Georgina was born on 11th November 2007 and is running late for her two month old vaccinations. She is brought to the medical centre on 4th March 2008 for her first round of scheduled vaccinations; she is now 16 weeks of age. She has missed the RotaTeq cut-off date therefore cannot receive RotaTeq.

- Give dose one of Infanrix hexa and Prevenar.
- Book Georgina in for her second round of scheduled vaccines (Infanrix hexa and Prevenar) for one month time. Do not administer RotaTeq vaccine.

Scenario 3
Baby Alice has presented on time for her 4 month old vaccines on 15th March 2008. At two months Alice was given RotaTeq, Infanrix IPV, Comvax and Prevenar vaccines as scheduled.

- Give now RotaTeq, Infanrix hexa, and Prevenar.
- Return at six months for RotaTeq, Infanrix hexa, and Prevenar.
- At 12 months of age administer Priorix, NeisVacC and Hiberix.

Scenario 4
Baby Louis, born on 7th September 2007 was vaccinated on time at two and four months, and is brought by his mother for his six months old vaccinations on 7th March. He has been a bit irritable this morning but clinical assessment is otherwise unremarkable. He is breastfeeding well.

- There is no contraindication to vaccination. Louis should be vaccinated with all due scheduled vaccines i.e. Infanrix hexa, Prevenar and RotaTeq.
- In six months time administer the twelve month old vaccines Priorix, NeisVacC and Hiberix.

Scenario 5
Baby Ben was born on 17th April 2007 and has been fully immunised to date. He is brought in to the clinic for his twelve month vaccinations on 18th April 2008.

- Administer dose three of Comvax and dose one of Priorix and NeisVacC.
- Book him in for his 18 month Varilrix, in six months time.

Scenario 6
Rebecca was born in New South Wales on 20th December 2007. At her routine immunisations at eight weeks of age, Rebecca received Infanrix hexa, Prevenar and Rotarix vaccines. At three months of age her family located to Victoria. What vaccines are due at four, six and twelve months of age?

- At four months of age Rebecca should receive Infanrix hexa, Prevenar & RotaTeq.
- At six months of age Rebecca should receive Infanrix hexa, Prevenar & RotaTeq.
- At 12 months of age Rebecca should receive Priorix, NeisVacC and Hiberix.

Scenario 7
Daniel was born on 19th August 2007 and has been fully immunised to date using Infanrix IPV (two, four and six months) and Comvax (two and four months) vaccines. He is brought in to the clinic for his twelve month old vaccinations on 19th August 2008. There is no Comvax vaccine available.

- Administer Priorix, NeisVacC, Hiberix and hepatitis B.
- Book him in for his 18 month old Varilrix, in six months time.

Scenario 8
Emily was born on the 24th May 2003 and presents at your session on the 20th March 2008. She is 4 years and 10 months old and has never been immunised.

- Administer dose one of Infanrix hexa, Priorix and NeisVacC today.
- In one month give Emily dose two of Infanrix IPV, HB VaxII Paediatric and Priorix.
- One month later give Emily dose three of Infanrix IPV.
- The booster dose of paediatric hepatitis B vaccine is given a minimum two months after dose two.
- To complete the vaccine catch-up administer dose four of Infanrix IPV six months after dose three.
Infanrix hexa vaccine is used for primary immunisation at two, four and six months of age and can be given if an infant has had part of their primary schedule with Infanrix IPV at two and/or four months of age.

Infanrix hexa contains six antigens:
- Diphtheria
- Tetanus
- Pertussis (acellular)
- Poliomyelitis (inactivated)
- Hepatitis B
- Haemophilus influenzae type b (Hib)

Infanrix hexa is presented as a syringe containing 0.5ml of diphtheria, tetanus, acellular pertussis, hepatitis B and inactivated poliomyelitis vaccine plus a vial containing a lyophilised pellet of Haemophilus influenzae type b.

Infanrix hexa vaccine must be reconstituted by adding the entire contents of the syringe to the vial and shaking until the pellet is completely dissolved.

Hiberix vaccine contains the antigen Haemophilus influenzae type b (Hib) and is administered at the 12 month schedule as a booster dose for Hib. Children up to the fifth birthday who are not immunised as babies should be given Hib vaccine if they have not received a complete Hib course. Overdue children aged 15 months to less than five years of age only require a single dose of the Hib antigen. If they are commencing a primary schedule they should be given Infanrix hexa as the first dose followed by Infanrix IPV and HB VaxII Paediatric as per the recommended catch-up schedule.

The Hiberix vaccine consists of Haemophilus influenzae type b purified polysaccharide (PRP) from the Hib capsule conjugated to the carrier protein tetanus toxoid. The PRP-T vaccine is a four dose course; three primary doses of Hib in the combination vaccine Infanrix hexa plus one booster dose of Hib at 12 months of age (Hiberix).

Hiberix vaccine must be reconstituted by adding the entire contents of the syringe to the vial and shaking until the pellet is completely dissolved.

What happens when Comvax runs out?

When there is no Comvax (Hib and hepatitis B) vaccine left for babies at 12 months of age, the babies who have previously received Infanrix-IPV at two, four and six months and Comvax at two and four months will need to be given separate doses of Hiberix vaccine and hepatitis B vaccine to ensure they receive sufficient doses of all antigens.

This will mean a cohort of babies who have completed their six month old schedule and not yet received 12 month old vaccines, will be given four injections as follows: Priorix, NeisVac C, Hiberix and HBVax11 paediatric.
The Australian Technical Advisory Group on Immunisation (ATAGI) recommended that, for Indigenous children at risk of early invasive Hib disease (namely WA and NT), the preferred approach remains to give PRP-OMP either as monovalent vaccine or as COMVAX in the standard two, four, 12 schedule. ATAGI was informed that supplies of PRP-OMP vaccine for WA and NT will be sufficient to continue the existing PRP-OMP based schedule.

In jurisdictions currently using PRP-OMP (namely QLD, SA and Vic), where pre-Hib vaccine introduction early onset invasive disease in Indigenous infants was not of the same level as in NT and WA, ATAGI believes that replacement of PRP-OMP schedule with an appropriate PRP-T vaccine based schedule is acceptable.

If vaccine supplies of PRP-OMP are further restricted, use of a PRP-T vaccine for the 12-month booster in infants primed with PRP-OMP vaccine would be appropriate. While theoretically sound and efficacious, ATAGI does not believe that a mixed primary course schedule (e.g. dose 1 at 2 months with PRP-OMP and doses 2 and 3 at 4 and 6 months with PRP-T) should be recommended because of its complexity. However, jurisdictions may wish to switch to PRP-T for all children in the progress of their primary course at a fixed date for reasons of simplicity for providers, recognizing that a total of three doses will be required for the primary course for those children who have not received two doses of PRP-OMP.

ATAGI stressed that this recommendation applied only during the period of shortage and recommended that the incidence of invasive Hib disease and the effect of vaccine substitution continue to be carefully monitored in these populations during this time.

**ATAGI advice to the impending Comvax shortage**

**Prevent Comvax wastage**

- Comvax (Hib and hepatitis B) needs to be conserved for the 12 month old scheduled vaccines.
- Monitor vaccine storage carefully to prevent cold chain breaches (Strive for 5°C).
- From 1 March only use Comvax for the 12 month old scheduled doses.
- Only order stock to be used for the next month.
- Local councils should not over draw vaccine in the community sessions.

**HPV Vaccine resources**

**HPV pre-immunisation advice sheet**


The HPV pre-immunisation advice sheet is for young women prior to Gardasil® vaccination along with the HPV vaccine brochure to assist in the informed consent procedure.

**HPV vaccine brochure** *(Protecting yourself from cervical cancer)*

Order by calling the Australian Government information line on 1800 671 811.

**HPV pre-immunisation advice sheet** *(tear-off pad of 100 sheets) for local councils.*

Provided to parents along with the HPV school consent card and the HPV brochure for parents *(Protecting your daughter from cervical cancer).*


**Human Papillomavirus (HPV) Vaccine**

Possible immunisation reactions to the human papillomavirus vaccine:

Common side effects following immunisation are usually mild and last one to two days. Treatment is not usually required. Paracetamol and the placement of a cool, moist cloth over the injection site may assist with discomfort. If the side effect is uncommon, severe or persistent, or if you are worried about you or your child’s condition, contact your doctor or hospital.

Common side effects:
- Pain, redness and swelling at the injection site
- Low grade temperature
- Feeling unwell
- Headache
- Five to 30 minutes following any vaccination, fainting may occur

Uncommon side effects:
- Rash or hives

Rare side effect:
- Severe allergic reaction, i.e. facial swelling, difficulty breathing.

In the event of a severe allergic reaction, please seek immediate medical attention.

It is recommended that anyone who has a rash or hives after a vaccine should discuss this with their immunisation provider before having further doses of that same vaccine.

Please contact your immunisation provider for further enquiries if required.
National HPV Vaccination Program

4 Key points
1. Reminder to all providers that, as with all vaccines, anaphylaxis can occur rarely and therefore it is important that emergency equipment including adrenaline is available at the time of vaccination.
2. Patients should be observed for at least 15 minutes after vaccination.
3. Any patient who experiences an allergic reaction should not be given any further doses until specialist medical advice has been sought. SAEFVIC can be contacted for such advice on 1300 882 924 or on the website http://www.health.vic.gov.au/immunisation/general/saefvic
4. Further advice has been posted on the TGA website www.tga.gov.au/alerts/medicines/gardasil.htm

School based vaccine program - 7 tips to avoid mass psychogenic illness

Vaccination is a medical procedure requiring a calm, orderly process to assess each student through vaccine consent and administration. In order to minimise the possibility of clusters of children in the same school experiencing a high degree of anxiety leading to side effects the following actions are recommended. These actions are best implemented by councils at the time of booking dates to attend the school.

1. Organise sessions to be run in a venue that allows privacy for each student being vaccinated so that other students are not watching the procedure prior to their vaccine being administered.
2. The venue should also provide a nearby area for adolescents to wait following the vaccination. This area needs to be readily accessible to immunisation staff in the event of a faint or other immediate adverse event.
3. The vaccination area should be free of staircases and concrete as these areas can contribute to injury following a fainting episode.
4. It is important for a person familiar to each class to be present at the venue in order to assist with identification of children and control their behaviour and create a calm environment.
5. Ensure the vaccine session is run with only one class present at a time to minimise the sense of mass anxiety that a few students can engender in other vulnerable students.
6. Following vaccination, students are required to wait a minimum of 15 minutes in a nearby location however this time should be longer if a student is feeling dizzy or unwell after vaccination.
7. Following vaccination, adolescents should refrain from strenuous activity and driving (eg. Year 12 students) for up to 30 minutes in the event of a delayed fainting episode.

HPV catch-up when doses are missed

Do not repeat earlier doses of Gardasil® vaccine.

If the recommended time intervals have been exceeded, give the missing dose(s) as soon as practicable, making efforts to complete the schedule within 12 months and maintaining the following minimum intervals.

<table>
<thead>
<tr>
<th>Gardasil recommended intervals</th>
<th>Gardasil minimum intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose 1 = Initial dose</td>
<td>Dose 1 = Initial dose</td>
</tr>
<tr>
<td>Dose 2 = Two months after the initial dose</td>
<td>Dose 2 = One month after the initial dose</td>
</tr>
<tr>
<td>Dose 3 = Four months after dose two</td>
<td>Dose 3 = Three months after dose two</td>
</tr>
</tbody>
</table>

Contact
For further information on the Immunisation Program please contact:

Immunisation Program, Department of Human Services
50 Lonsdale Street, Melbourne 3000

Phone: 1300 882 008
Fax: 1300 768 088
Email: immunisation@dhs.vic.gov.au