### Maklumat tambahan indikasi untuk upload pada laman web

**Year 2016**

**Products Approved For Additional Indication (DCA 305 – 31 Oktober 2016)**

<table>
<thead>
<tr>
<th>NO</th>
<th>PRODUCT (ACTIVE INGREDIENT)</th>
<th>ADDITIONAL INDICATION</th>
<th>MARKETING AUTHORIZATION HOLDER</th>
</tr>
</thead>
</table>
| 1. | **1.1 Eligard 7.5mg Powder & Solvent for Solution For Injection**

[7.5 mg leuprorelin acetate, equivalent to 6.96 mg leuprorelin] | Indication:

*ELIGARD* is indicated for the treatment of high-risk localized and locally advanced hormone dependent prostate cancer in combination with radiotherapy. |

DKSH MALAYSIA SDN. BHD.
B-11-01, The Ascent, Paradigm No. 1, Jalan SS7/26A, Kelana Jaya 47301 Petaling Jaya, Selangor|
| 2. | **1.2 Eligard 22.5mg Powder & Solvent for Solution For Injection**

[22.5 mg leuprorelin acetate, equivalent to 20.87 mg leuprorelin] | Posology:

*ELIGARD* may be used as neoadjuvant or adjuvant therapy in combination with radiotherapy in high-risk localised and locally advanced prostate cancer. |
| 3. | **1.3 Eligard 45mg Powder & Solvent for Solution For Injection**

[45 mg leuprorelin acetate, equivalent to 41.7 mg leuprorelin] | Paediatric population

Safety and efficacy in children under the age of 18 years have not been established. |
| 2. | **2.1 Cosentyx 150mg Powder for solution for injection**

[Secukinumab 150mg/vial] | Indication:

*Ankylosing spondylitis*  
*Cosentyx* is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. |

NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor|
| 3. | **2.2 Cosentyx 150mg/ml solution for injection in pre-filled pen**

[Secukinumab 150mg/vial] | Posology:

*Ankylosing spondylitis*  
The recommended dose is 150mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. |
| 4. | **2.3 Cosentyx 150mg/ml solution for injection in pre-filled syringe**

[Secukinumab 150mg/vial] |  |
### SYNFLORIX VACCINE

[1 dose (0.5ml) contains:

1 mcg Streptococcus (S) Pneumonia polysaccharide serotype 1,2
3 mcg S. Pneumonia polysaccharide serotype 4,1,2
1 mcg S. Pneumonia polysaccharide serotype 5,1,2
1 mcg S. Pneumonia polysaccharide serotype 6B,1,2
1 mcg S. Pneumonia polysaccharide serotype 7F,1,2
1 mcg S. Pneumonia polysaccharide serotype 9V,1,2
1 mcg S. Pneumonia polysaccharide serotype 14,1,2
3 mcg S. Pneumonia polysaccharide serotype 18C,1,3
3 mcg S. Pneumonia polysaccharide serotype 19F,1,4
1 mcg S. Pneumonia polysaccharide serotype 23F,1,2

1 adsorbed on aluminium phosphate
2 conjugated to protein D (derived from NTHi) carrier protein
3 conjugated to tetanus toxoid carrier protein
4 conjugated to diphtheria toxoid carrier protein]

<table>
<thead>
<tr>
<th>➢ Indication:</th>
</tr>
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<tbody>
<tr>
<td>Active immunisation of infants and children from 6 weeks up to 5 years of age against disease caused by Streptococcus pneumoniae serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F and cross-reactive serotype 19A (including sepsis, meningitis, pneumonia, bacteraemia and acute otitis media) and against acute otitis media caused by Non-Typeable Haemophilus influenza.</td>
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GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.
Level 6, Quill 9, 112, Jalan Semangat No.8, Persiaran Tropicana 46300 Petaling Jaya, Selangor