Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 382, 2 Mac 2023

Products approved for additional indication (DCA 382 – 2 March 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Opdivo 10mg/ml, Concentrate for solution for infusion [Nivolumab 10mg/ml]	**INDICATION :** Gastric, gastro-oesophageal junction (GEJ) or oesophageal adenocarcinoma OPDIVO in combination with fluoropyrimidine- and platinum-based combination chemotherapy is indicated for the first-line treatment of adult patients with HER2-negative advanced or metastatic gastric, gastro-oesophageal junction or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) ≥ 5. **POSOLOGY :** Treatment must be initiated and supervised by physicians experienced in the treatment of cancer. <u>PD-L1 testing</u> If specified in the indication, patient selection for treatment with OPDIVO based on the tumour expression of PD-L1 should be confirmed by a validated test (see sections 4.1, 4.4, and 5.1 of the package insert). <u>OPDIVO in combination with chemotherapy</u> <u>Gastric, gastro-oesophageal junction or oesophageal adenocarcinoma</u> The recommended dose is 360 mg nivolumab administered intravenously over 30 minutes in combination with fluoropyrimidine- and platinum-based chemotherapy administered every 3 weeks or 240 mg nivolumab administered intravenously over 30 minutes in combination with fluoropyrimidine- and platinum-based chemotherapy administered every 2 weeks (see section 5.1). Treatment with nivolumab is recommended until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.	**DKSH MALAYSIA SDN. BHD.** B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		When OPDIVO is administered in combination with chemotherapy, refer to the package insert of the other combination therapy agents regarding dosing. If any agents are withheld, the other agents may be continued. If dosing is resumed after a delay, either the combination treatment, OPDIVO monotherapy or chemotherapy alone could be resumed based on the evaluation of the individual patient. <u>Method of administration</u> OPDIVO is for intravenous use only. It is to be administered as an intravenous infusion over a period of 30 minutes. The infusion must be administered through a sterile, non-pyrogenic, low protein binding in-line filter with a pore size of 0.2-1.2 µm. OPDIVO must not be administered as an intravenous push or bolus injection. The total dose of OPDIVO required can be infused directly as a 10 mg/mL solution or can be diluted to as low as 1 mg/mL with sodium chloride 9 mg/mL (0.9%) solution for injection or glucose 50 mg/mL (5%) solution for injection. When administered in combination with chemotherapy, OPDIVO should be given first followed by chemotherapy on the same day. Use separate infusion bags and filters for each infusion.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	**INDICATION :** KEYTRUDA as monotherapy is indicated for the adjuvant treatment of adult and paediatric (12 years and older) patients with Stage IIB, IIC or III melanoma who have undergone complete resection. **POSOLOGY :** Pediatric Patients In **melanoma and** cHL, the recommended dose of KEYTRUDA in pediatric patients is 2 mg/kg (up to a maximum of 200 mg), administered as an intravenous infusion over 30 minutes every 3 weeks. Renal Impairment No dose adjustment is needed for patients with mild or moderate renal impairment. KEYTRUDA has not been studied in patients with severe renal impairment. Hepatic Impairment No dose adjustment is needed for patients with mild hepatic impairment. KEYTRUDA has not been studied in patients with moderate or severe hepatic impairment.	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 382, 2 Mac 2023

Products approved for additional indication (DCA 382 – 2 March 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	Pagenax 120mg/ml Solution For Injection [Brolucizumab 120mg/ml]	**INDICATION :** Pagenax is indicated in adults for the treatment of visual impairment due to diabetic macular oedema (DME). **POSOLOGY :** Pagenax must be administered by a qualified ophthalmologist experienced in intravitreal injections. Posology DME The recommended dose is 6 mg brolucizumab (0.05 ml solution) administered by intravitreal injection every 6 weeks for the first 5 doses. Thereafter, the physician may individualise treatment intervals based on disease activity as assessed by visual acuity and/or anatomical parameters. In patients without disease activity, treatment every 12 weeks (3 months) should be considered. In patients with disease activity, treatment every 8 weeks (2 months) should be considered. If visual and anatomical outcomes indicate that the patient is not benefiting from continued treatment, Pagenax should be discontinued.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 382, 2 Mac 2023

Products approved for additional indication (DCA 382 – 2 March 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Dupixent 300 mg Solution for Injection in Pre-filled Syringe [Dupilumab 300mg]	**INDICATION :** <u>Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)</u> Dupixent is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adults with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control **POSOLOGY :** <u>Recommended Dosage for Chronic Rhinosinusitis with Nasal Polyposis</u> The recommended dosage of DUPIXENT for adult patients is 300 mg given every other week. Missed Doses If an every other week dose is missed, administer the injection within 7 days from the missed dose and then resume the patient's original schedule. If the missed dose is not administered within 7 days, wait until the next dose on the original schedule. If an every 4 week dose is missed, administer the injection within 7 days from the missed dose and then resume the patient's original schedule. If the missed dose is not administered within 7 days, administer the dose, starting a new schedule based on this date. Preparation for use Before injection, remove DUPIXENT pre-filled syringe from the refrigerator and allow DUPIXENT to reach room temperature (45 minutes for the 300 mg/2 mL pre-filled syringe and 30 minutes for the 200 mg/1.14 mL pre-filled syringe) without removing the needle cap. After removal from the refrigerator, DUPIXENT must be used within 14 days or discarded.	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** Unit TB-18-1, Level 18, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 382 – 2 March 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Inspect DUPIXENT visually for particulate matter and discoloration prior to administration. DUPIXENT is a clear to slightly opalescent, colorless to pale yellow solution. Do not use if the liquid contains visible particulate matter, is discolored or cloudy (other than clear to slightly opalescent, colorless to pale yellow). DUPIXENT does not contain preservatives; therefore, discard any unused product remaining in the pre-filled syringe. DUPIXENT is administered by subcutaneous injection.	
5.	Taltz 80mg solution for injection in pre-filled syringe Taltz 80mg solution for injection in pre-filled pen [Ixekizumab 80 mg]	**INDICATION :** <u>Paediatric plaque psoriasis</u> Taltz is indicated for the treatment of moderate to severe plaque psoriasis in children from the age of 6 years and with a body weight of at least 25 kg and adolescents who are candidates for systemic therapy. **POSOLOGY :** Paediatric plaque psoriasis (age 6 years and above) Efficacy and safety data is not available in children below the age of 6 years (see section 5.1). Available data do not support a posology below a body weight of 25 kg. The recommended dose given by subcutaneous injection in children is based on the following weight categories:	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.

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Products approved for additional indication (DCA 382 – 2 March 2023)

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<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Children’s Body Weight</td><td>Recommended Starting Dose (Week 0)</td><td>Recommended Dose every 4 weeks (Q4W) thereafter</td></tr>
<tr><td>Greater than 50 kg</td><td>160 mg (two 80 mg injections)</td><td>80 mg</td></tr>
<tr><td>25 to 50 kg</td><td>80 mg</td><td>40 mg</td></tr>
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For children prescribed 80 mg, Taltz can be used directly from the prefilled syringe.

For instructions on preparation of Taltz 40 mg, see section 6.6. Doses less than 80 mg must be prepared by a healthcare professional.

Taltz is not recommended for use in children with a body weight below 25 kg. Paediatric body weights must be recorded and regularly re -checked prior to dosing
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