Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 395, 4 April 2024

Products approved for additional indication (DCA 395 – 4 April 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Jardiance 10mg film coated tablets [Empagliflozin 10mg]	**INDICATION :** Chronic kidney disease Jardiance is indicated in adults for the treatment of chronic kidney disease. **POSOLOGY :** Chronic kidney disease The recommended dose is 10 mg empagliflozin once daily. Special populations <u>Renal impairment</u> Due to limited experience, it is not recommended to initiate treatment with empagliflozin in patients with an eGFR <20 ml/min/1.73 m^2. In patients with type 2 diabetes mellitus, the glucose lowering efficacy of empagliflozin is reduced in patients with an eGFR <45 ml/min/1.73 m^2 and likely absent in patients with an eGFR<30 ml/min/1.73 m^2. Therefore, if eGFR falls below 45 ml/min/1.73m^2, additional glucose lowering treatment should be considered if needed.	**BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.** Suite 15-5 Level 15, Wisma UOA Damansara II, No 6, Jalan Changkat Semantan,Damansara Heights, 50490 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Fraizeron 150mg Powder for Solution for Injection Fraizeron 150mg/ml solution for injection in pre-filled pen Fraizeron 300mg/2ml solution for injection in pre-filled pen Cosentyx 150mg/ml solution for injection in pre-filled syringe [Secukinumab 150mg/mL]	**INDICATION :** Hidradenitis Suppurativa (HS) Fraizeron/Cosentyx is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **POSOLOGY:** The recommended dose is 300 mg of secukinumab by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. Each 300 mg dose is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	Darzalex Faspro 1,800 mg solution for injection [Daratumumab 1800 mg[	**INDICATION:** DARZALEX FASPRO is indicated for the treatment of adult patients with multiple myeloma: • in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy **POSOLOGY:** <u>Dosage – Adults (≥18 years)</u> Recommended dose for multiple myeloma The DARZALEX FASPRO dosing schedule in Table 1 is for combination therapy with 4-week cycle regimens (e.g. lenalidomide, **pomalidomide**, carfilzomib) and for monotherapy as follows: • combination therapy with lenalidomide and low-dose dexamethasone for patients with newly diagnosed multiple myeloma ineligible for autologous stem cell transplant (ASCT) • combination therapy with lenalidomide or **pomalidomide** and low-dose dexamethasone for patients with relapsed/refractory multiple myeloma • combination therapy with carfilzomib and low-dose dexamethasone for patients with relapsed/refractory multiple myeloma • monotherapy for patients with relapsed/refractory multiple myeloma The recommended dose is DARZALEX FASPRO 1800 mg administered subcutaneously, over approximately 3-5 minutes, according to the following dosing schedule: **Table 1: DARZALEX FASPRO dosing schedule in combination with lenalidomide [Rd], pomalidomide [Pd] or carfilzomib [Kd] and dexamethasone (4-week cycle) and for monotherapy**	**JOHNSON & JOHNSON SDN. BHD.** Level 8, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 46150 Petaling Jaya, Selangor.

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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><th>Weeks</th><th>Schedule</th></tr>
<tr><td>Weeks 1 to 8</td><td>weekly (total of 8 doses)</td></tr>
<tr><td>Weeks 9 to 24[a]</td><td>every two weeks (total of 8 doses)</td></tr>
<tr><td>Week 25 onwards until disease progression[b]</td><td>every four weeks</td></tr>
<tr><td colspan="2">[a] First dose of the every-2-week dosing schedule is given at Week 9
[b] First dose of the every-4-week dosing schedule is given at Week 25</td></tr>
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