Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 400, 5 September 2024

Products approved for additional indication (DCA 400 – 5 September 2024)

N	lo.	Product [Active Ingredient]	Additional Indication	Product Registration
1.		Product [Active Ingredient] Imbruvica 140mg Capsules Imbruvica 140mg Capsules IMBRUVICA 140 mg film-coated tablets [Ibrutinib 140mg] IMBRUVICA 280 mg film-coated tablets [Ibrutinib 280mg] IMBRUVICA 420 mg film-coated tablets [Ibrutinib 420mg]	INDICATION: IMBRUVICA is indicated for the treatment of adult patients with mantle cell lymphoma (MCL). POSOLOGY: The recommended dose for the treatment of MCL is 560 mg once daily until disease progression or no longer tolerated by the patient. For MCL, IMBRUVICA can be administered in combination with bendamustine and rituximab (BR) for patients with previously untreated MCL or as a single agent for patients with relapsed or refractory MCL. For additional information concerning BR see the corresponding rituximab or bendamustine prescribing information.	Product Registration Holder (PRH) JOHNSON & JOHNSON SDN. BHD. Level 8, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 46150 Petaling Jaya, Selangor.

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١	lo.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2	2.	BRUKINSA 80 mg capsules [Zanubrutinib 80 mg]	INDICATION: BRUKINSA as monotherapy is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL).	BEIGENE MALAYSIA SDN. BHD. Level 13, Menara 1 Sentrum, 201, Jalan Tun Sambanthan, Brickfields, 50470 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.
3	3.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	INDICATION: Gastric Cancer KEYTRUDA, in combination with fluoropyrimidine and platinum-containing chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥1. KEYTRUDA, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with CPS ≥1.	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.