Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 404, 16 Januari 2025

Products approved for additional indication (DCA 404 – 16 Januari 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Alecensa (Alectinib) Hard Capsules 150mg [Alectinib 150 mg (equivalent to 161.3 mg alectinib hydrochloride)]	**INDICATION :** Adjuvant treatment of resected non small cell lung cancer (NSCLC) Alecensa is indicated as adjuvant treatment following tumor resection for patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC). **POSOLOGY :** No changes to the recommended dose, however below statement is added. <u>Duration of treatment</u> Adjuvant treatment of resected NSCLC Treatment with Alecensa should be continued until disease recurrence, unacceptable toxicity or for 2 years.	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 404, 16 Januari 2025

Products approved for additional indication (DCA 404 – 16 Januari 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	ROMIPLATE 250 µg INJECTION [Romiplastim 250mcg/ vial]	**INDICATION :** <u>Chronic immune (idiopathic) thrombocytopenic purpura (ITP)</u> Romiplate® is indicated for adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)	**KYOWA KIRIN MALAYSIA SDN. BHD.** Suite A501, 5th Floor, West Wing, Wisma Consplant 2, No. 7, Jalan SS 16/1, 47500 Subang Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 404, 16 Januari 2025

Products approved for additional indication (DCA 404 – 16 Januari 2025)

<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>3.</td><td>MIRCERA SOLUTION FOR INJECTION IN PRE FILLED SYRINGE, 50MCG/0.3ML

MIRCERA SOLUTION FOR INJECTION IN PRE FILLED SYRINGE, 100MCG/0.3ML

MIRCERA SOLUTION FOR INJECTION IN PRE FILLED SYRINGE, 75MCG/0.3ML

MIRCERA SOLUTION FOR INJECTION IN PRE FILLED SYRINGE, 150MCG/0.3ML

MIRCERA SOLUTION FOR INJECTION IN PRE FILLED SYRINGE, 200MCG/0.3ML

MIRCERA SOLUTION FOR INJECTION IN PRE FILLED SYRINGE, 120mcg/0.3mL

[Methoxy polyethylene glycol-epoetin beta]</td><td>INDICATION :

Mircera is indicated for the treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in paediatric patients from 3 months to less than 18 years of age who are converting from another erythropoiesis stimulating agent (ESA) after their haemoglobin level was stabilized with the previous ESA.

POSOLOGY :

Paediatric patients from 3 months to less than 18 years of age currently treated with an ESA:

Paediatric patients whose haemoglobin level has been stabilized by treatment with an ESA can be converted to methoxy polyethylene glycol-epoetin beta administered once every 4 weeks as an IV or SC injection, but keeping the same administration route. The starting dose of methoxy polyethylene glycol-epoetin beta is calculated based on the total weekly ESA dose at the time of conversion (Table 2).

Table 2: Methoxy polyethylene glycol-epoetin beta starting doses for paediatric patients from 3 months to less than 18 years of age currently receiving an ESA

<table><tr><th>Previous weekly epoetin dose (IU/week)</th><th>Every 4-week methoxy polyethylene glycol-epoetin beta dose (microgram)</th></tr><tr><td>2700 - <3500</td><td>50</td></tr><tr><td>3500 - <5500</td><td>75</td></tr></table></td><td>ROCHE (MALAYSIA) SDN. BHD.
Level 21, The Pinnacle,
Persiaran Lagoon,
Bandar Sunway,
47500 Subang Jaya,
Selangor.</td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 404, 16 Januari 2025

Products approved for additional indication (DCA 404 – 16 Januari 2025)

<table>
<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>5500 - <6500</td><td>100</td></tr>
<tr><td>6500 - <8000</td><td>120</td></tr>
<tr><td>8000 - <10000</td><td>150</td></tr>
<tr><td>10000 - <13000</td><td>200</td></tr>
<tr><td>13000 - <20000</td><td>250</td></tr>
<tr><td>≥20000</td><td>360</td></tr>
</table>

Pre-filled syringes are not designed for administration of partial doses. Due to the available dose strengths of pre-filled syringes, paediatric patients with an ESA dose of < 2700 IU/week of epoetin, should not be switched to methoxy polyethylene glycol-epoetin beta.

If a dose adjustment is required to maintain the target haemoglobin concentration above 10 g/dL, the 4 weekly dose may be adjusted by approximately 25%.

If the rise in haemoglobin is greater than 1 g/dL (0.62 mmol/L) over 4 weeks or the haemoglobin level is increasing and approaching 12 g/dL (7.45 mmol/L), the methoxy polyethylene glycol-epoetin beta dose is to be reduced by approximately 25%.

If the haemoglobin level continues to increase following dose reduction, therapy is to be interrupted until the haemoglobin level begins to decrease, at which point therapy should be restarted at a dose approximately 25% below the previously administered dose.</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 404, 16 Januari 2025

Products approved for additional indication (DCA 404 – 16 Januari 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Dose adjustments should not be made more often than once every 4 weeks. **Special Dosage Instructions** Pediatric use: The safety and efficacy of methoxy polyethylene glycol-epoetin beta in paediatric patients less than 3 months of age have not been established. No data are available.	