

## 6.18 METHYLPHENIDATE

**Capsule containing methylphenidate hydrochloride  
10 mg, 20 mg, 30 mg 40 mg and 60 mg (modified  
release),  
Ritalin® LA,  
Novartis Pharmaceuticals Australia Pty Limited.**

### 1 Purpose of Application

- 1.1 The Category 3 submission requested expanding the current General Schedule Authority Required listing of methylphenidate 10 mg, 20 mg, 30 mg, 40 mg and 60 mg modified release capsules, Ritalin LA®, to include adult patients with a retrospective diagnosis of attention deficit hyperactivity disorder (ADHD) under the same population criteria as the currently listed lisdexamfetamine (LDX).

### 2 Background

#### *TGA registration status*

- 2.1 Ritalin LA® first listed (20 mg, 30 mg and 40 mg capsules) on the Australian Register of Therapeutic Goods (ARTG) on 21 August 2002. Subsequent inclusions were added on 18 December 2009 (10 mg capsules) and 11 March 2016 (60 mg capsules). All strengths are indicated for the treatment of ADHD with no reference made to the age of diagnosis.

#### *Previous PBAC consideration*

- 2.2 Ritalin LA is listed on the PBS for the treatment of ADHD in patients diagnosed between 6 and 18 years (inclusive).
- 2.3 At the March 2020 PBAC meeting, the PBAC recommended expanding the listing of LDX in ADHD based on, among other matter, its assessment that the cost-effectiveness of LDX in adults would be acceptable if LDX was no more costly on a per day basis (at ex-manufacturer price) for this population than the drug cost per patient per day of immediate release dexamfetamine. The PBAC also advised a flow-on changes to all other long-acting ADHD medicines on the PBS, including methylphenidate hydrochloride (Concerta® and Ritalin LA®) and atomoxetine (e.g. Strattera®) to include treatment of patients with ADHD who are diagnosed after the age of 18, and at a similarly reduced price to LDX, based on the accepted weighting of 28% diagnosed after the age of 18 years and 72% diagnosed before the age of 18.

**Current situation**

2.4 The sponsor noted that on 8 July 2021, it was approached by the Department regarding expansion of Ritalin LA to include treatment of patients diagnosed after the age of 18 at a reduced price.

2.5 The prices that were calculated by the Department are set out in Table 1 below.

**Table 1: Calculated price of Ritalin LA**

Strength, Qty	Column A Existing AEMP (diagnosed before age 18) (72%)	Column B AEMP for diagnosed after age 18 (28%) (Column A / 72 * 28)	Column C New AEMP required (Column A * 0.72 + Column B * 0.28)	% reduction required
Ritalin LA 10 mg, 30	\$20.15	\$7.84	\$16.70	17.11%
Ritalin LA 20 mg, 30	\$28.78	\$11.19	\$23.86	17.11%
Ritalin LA 30 mg, 30	\$35.71	\$13.89	\$29.60	17.11%
Ritalin LA 40 mg, 30	\$38.07	\$14.81	\$31.56	17.11%
Ritalin LA 60 mg, 30	\$51.01	\$19.84	\$42.28	17.11%

2.6 On 16 July 2021, the sponsor advised it was unable to accept the proposed price reduction of 17.11%. The sponsor requested the flow-on restriction change be implemented with no price reduction.

2.7 On 29 July 2021, the Department outlined to the sponsor that it was not in a position to recommend the flow-on restriction change to the Minister without a price reduction being offered based on the explicit advice of the PBAC’s consideration of LDX at its March 2020 meeting.

*For more detail on PBAC’s view, see section 5 PBAC outcome.*

**3 Requested listing**

3.1 The submission proposed the following changes to the restriction for Ritalin LA. Suggested additions are in *italics* and deletions are in strikethrough.

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Name, Restriction, Manner of administration and form	PBS item code	Max. Qty packs	Max. Qty units	№.of Rpts	Proprietary Name and Manufacturer
METHYLPHENIDATE					
methylphenidate hydrochloride 10 mg modified release capsule, 30	3440C	1	30	5	Ritalin LA Novartis Pharmaceuticals Australia Pty Ltd
methylphenidate hydrochloride 20 mg modified release capsule, 30	2276T	1	30	5	
methylphenidate hydrochloride 30 mg modified release capsule, 30	2280B	1	30	5	
methylphenidate hydrochloride 40 mg modified release capsule, 30	2283E	1	30	5	
methylphenidate hydrochloride 60 mg modified release capsule, 30	12116Q	1	30	5	

Restriction Summary: 10829 / ToC: 10719

<b>Category/Program:</b> Section 100 Efficient Funding of Chemotherapy
<b>Prescriber type:</b> <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Restriction level:</b> <input checked="" type="checkbox"/> Authority required - Streamlined (9895)
<b>Administrative Advice:</b> <b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
<b>Administrative Advice:</b> In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.
<b>Administrative Advice:</b> Care must be taken to comply with the provisions of State/Territory law when prescribing this drug
<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.
<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
<b>Indication:</b> Attention deficit hyperactivity disorder
<b>Population criteria:</b>
Patient must be <del>or have been diagnosed</del> aged between the ages of 6 and 18 years inclusive; OR
Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.
AND
<b>Clinical criteria:</b>
Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events

	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must require continuous coverage over 8 hours
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a maximum daily dose of 80 mg with this drug
	<b>Prescribing Instructions:</b>
	A retrospective diagnosis of ADHD for the purposes of administering this restriction is: <ul style="list-style-type: none"> <li>(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and</li> <li>(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above.</li> </ul>

- 3.2 The proposed changes to the restriction for Ritalin LA are consistent with the PBAC advice to align the restrictions of long-acting ADHD medicines.

*For more detail on PBAC's view, see section 5 PBAC outcome.*

## 4 Consideration of the evidence

### **Sponsor hearing**

- 4.1 There was no hearing for this item.

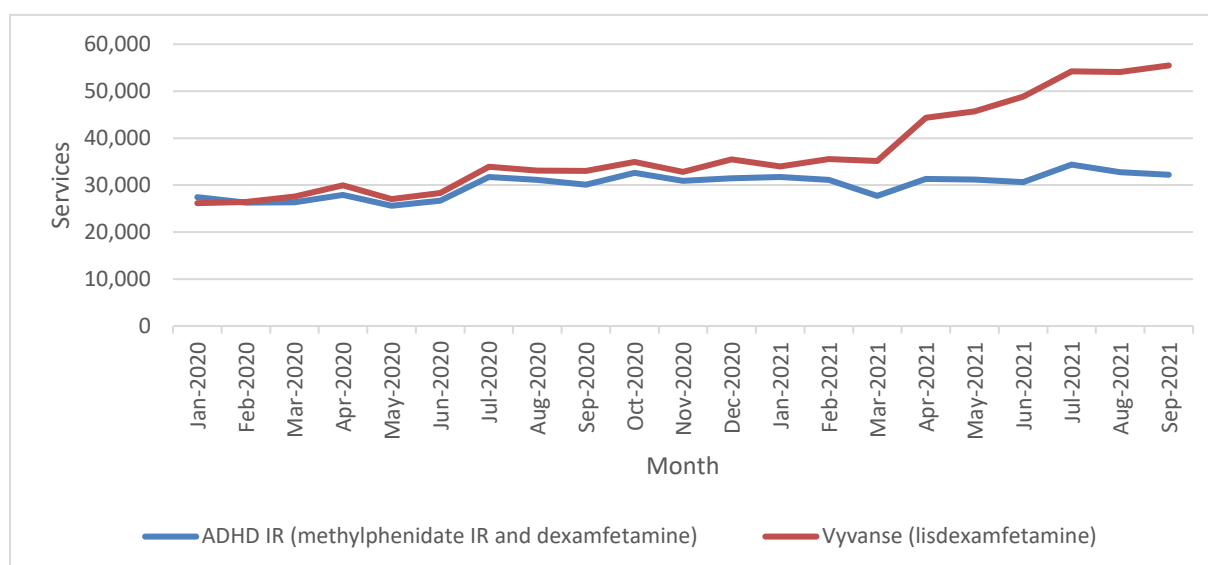
### **Consumer comments**

- 4.2 The PBAC noted and welcomed the input from individuals (131), health care professionals (21) and organisations (4) via the Consumer Comments facility on the PBS website. The comments from health care professionals described the benefits of treatment with Ritalin LA with respect to once daily dosing, such as improved compliance due to ease of use, and sustained response to the medication. Individuals described the significant improvements in quality of life due to Ritalin LA, but also the financial hardship associated with having to access the medication via a private prescription due to a diagnosis of ADHD in adulthood.
- 4.3 The PBAC also noted that ADHD Australia and ADHD Foundation were in strong support of the requested change to the listing. The comments emphasised that not all patients with ADHD are afforded the benefit of diagnosis in their early life. The organisations stated that it has been advocating for equity of access for long-acting ADHD medications for some time.

### **Use of the medicine in practice**

- 4.4 Per Figure 1, the submission noted that since the expansion of listing of LDX on the PBS on 1 February 2021, the gap between the PBS services of immediate-release methylphenidate and dexamfetamine (used in the treatment of ADHD with no age of diagnosis restriction) compared to the PBS services of LDX has widened.

Figure 1: ADHD IR and LDX PBS services prior to and after the change to restriction in February 2021



Source: Attachment\_1\_UCM-Ritalin LA\_adult\_ADHD, worksheet 'IR historical PBS'

- 4.5 In order to estimate the long-acting ADHD market for those diagnosed over 18 as characterised by the expansion of listing of LDX, the submission presented a historic and projected market-share comparative growth analysis of LDX against long-acting methylphenidate (of which Ritalin LA is a brand).
- 4.6 The submission noted that since the expansion of listing on 1 February 2021, LDX has experienced growth in PBS services at a substantially higher rate than long-acting methylphenidate (Table 2).

Table 2: Historical PBS services and growth for long-acting ADHD medications and projected for 2021

	2015	2016	2017	2018	2019	2020	2021*
<b>PBS Services</b>							
LDX	15,136	108,050	174,051	235,158	296,760	368,782	572,233
Long acting Methylphenidate**	510,886	486,471	501,550	528,703	576,559	648,803	712,463
Total	526,022	594,521	675,601	763,861	873,319	1,017,585	1,284,696
<b>Growth</b>							
LDX		613.9%	61.1%	35.1%	26.2%	24.3%	55.2%
Long acting Methylphenidate		-4.8%	3.1%	5.4%	9.1%	12.5%	9.8%
Total		13.0%	13.6%	13.1%	14.3%	16.5%	26.2%

Source: Table 2.5 of the submission main document

\* 2021 Services are pro-rata for methylphenidate and for lisdexamfetamine actual numbers from Jan-Sep, then 55,000 services each month for the remaining months (Oct-Dec) consistent with the increase in monthly volumes seen since the listing expansion in Feb 2021

\*\* Methylphenidate includes the extended-release forms available on the PBS, Ritalin LA and Concerta

- 4.7 The submission concluded that the substantial growth in utilisation of LDX since the expansion to listing, without a corresponding decrease in utilisation of immediate-release ADHD formulations (Figure 1) is evident that the source for new services was not coming from the immediate-release ADHD formulations that formed the basis for the price reduction in LDX.
- 4.8 The submission estimated a weighted average dose of Ritalin LA by age group using 10% sample PBS services from September 2020 to September 2021. Necessarily, the dose distribution in patients over 18 years old was based on those diagnosed prior to 18 years of age. The submission also estimated weighted average dose of LDX using PBS data prior to and after expansion to listing. These are presented in Table 3.
- 4.9 The submission argued that the difference in the average dose of Ritalin LA for those aged 18 and over (i.e. 30.26 mg) and for those aged under 18 (i.e. 27.06 mg) was minimal. The submission also noted the average LDX dose has not changed substantially since the listing expansion of LDX (43.10 mg versus 42.99 mg). The submission therefore assumed that any expansion to the Ritalin LA listing will result in minimal changes to the average dose used.

**Table 3: Ritalin LAs weighted average dose by age group based on PBS 10% sample scripts from September 2020 to September 2021 and LDX weighted average dose based on PBS statistics data prior to and after expansion to listing**

<b>Long acting methylphenidate</b>		
<b>Strength</b>	<b>Under 18 weighting (%)</b>	<b>18+ weighting (%)</b>
Ritalin LA 10mg	10.3%	9.5%
Ritalin LA 20mg	35.2%	23.7%
Ritalin LA 30mg	32.0%	27.9%
Ritalin LA 40mg	20.5%	35.7%
Ritalin LA 60mg	2.0%	3.2%
Total	100.0%	100.0%
<b>Weighted average dose (mg)</b>	<b>27.06</b>	<b>30.26</b>
<b>LDX</b>		
<b>Strength</b>	<b>Weighting prior to new listing (%)</b>	<b>Weighting after new listing (%)</b>
Vyvanse 20mg	6.4%	11.3%
Vyvanse 30mg	39.8%	31.0%
Vyvanse 40mg	5.9%	12.5%
Vyvanse 50mg	28.7%	23.2%
Vyvanse 60mg	2.5%	6.1%
Vyvanse 70mg	16.7%	16.0%
Total	100.0%	100.0%
<b>Weighted average dose (mg)</b>	<b>43.10</b>	<b>42.99</b>

Source: Table 2.3 and 2.4 of the submission main document

### **Pricing**

- 4.10 The submission argued that Ritalin LA (as a product on the F2 formulary) is already offered at a reasonable price which is assumed to be below the price of LDX even after the price reduction that took place following the expansion to listing.

- 4.11 The submission estimated the weighted average approved ex-manufacturer price (AEMP) of Ritalin LA using a weighted price across the different strengths of Ritalin LA and PBS data for the period of September 2020 to September 2021. The submission estimated the current effective AEMP of LDX based on the PBAC recommended 25% price cut to the effective AEMP and an assumed proportional reduction in the effective AEMP reflected with a 16% change in published price.
- 4.12 The submission estimated the effective AEMP of LDX to be \$41.33 and the weighted average price of Ritalin LA to be \$33.22 (Table 4).

**Table 4: Ritalin LA weighted price based on PBS statistics services from September 2020 to September 2021 and LDX published and estimated effective AEMP prior to and after price changes**

<b>Ritalin LA weighted price based on PBS statistics services from September 2020 to August 2021</b>				
Strength	AEMP	Services (Sep 2020-Sep 2021)	Weighting (%)	Weighted AEMP
Ritalin LA 10mg	\$20.15	15,545	5.5%	<b>\$33.22</b>
Ritalin LA 20mg	\$28.78	103,568	36.7%	
Ritalin LA 30mg	\$35.71	89,971	31.9%	
Ritalin LA 40mg	\$38.07	66,883	23.7%	
Ritalin LA 60mg	\$51.01	6,388	2.3%	
Total		282,355	100.0%	
<b>LDX published and estimated effective AEMP prior to and after price changes</b>				
Month	Percentage change to published AEMP	Published AEMP	Estimated effective AEMP	
January 2021	-	\$95.80	\$52.03	
February 2021	-16%	\$80.10	\$43.50	
April 2021 (current)	-5%	\$76.10	<b>\$41.33</b>	

Source: Table 2.1 and Table 2.2 of the submission main document.

***Estimated PBS utilisation and financial implications***

- 4.13 The submission used a market share approach to estimate utilisation and financial implications of Ritalin LA listing expansion using PBS prescription data for LDX.
- 4.14 The submission assumed an uptake rate of Ritalin LA of 20% in Year 1 of expanded listing, increasing to an uptake rate of 50% by Year 4. The submission also considered the number of LDX scripts displaced would be the same as the number of Ritalin LA scripts as both Ritalin LA and LDX are dispensed as a 30 pack.
- 4.15 The submission estimated the number of Ritalin LA scripts for the expanded population and the resulting financial implications using the following methodology (outlined in Table 5):

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- projected LDX PBS services for patients diagnosed with ADHD from 6 to 18 years, no change to existing listing (A).
- projected LDX PBS services for patients diagnosed with ADHD at all ages (B).
- projected LDX PBS services for patients diagnosed with ADHD after 18 years (C=B-A).
- Ritalin LA assumed uptake rate in patients diagnosed after 18 years (D).
- Total estimated Ritalin LA scripts (E=CxD).

Table 5: Estimated use and financial implications.

	2021	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Projected LDX PBS services for patients diagnosed from 6 to 18 years (no change to existing listing).</b>							
PBS Services (A)	█ <sup>1</sup>	█ <sup>2</sup>	█ <sup>7</sup>	█ <sup>7</sup>	█ <sup>4</sup>	█ <sup>8</sup>	█ <sup>11</sup>
Growth	22%	18%	15%	12%	10%	10%	10%
PBS Services (B)	█ <sup>*2</sup>	█ <sup>4</sup>	█ <sup>8</sup>	█ <sup>11</sup>	█ <sup>13</sup>	█ <sup>13</sup>	█ <sup>13</sup>
Growth	55%	25%	20%	15%	12%	10%	10%
<b>Projected LDX PBS services from diagnosed after 18</b>							
PBS Services (C)	█ <sup>3</sup>	█ <sup>3</sup>	█ <sup>9</sup>	█ <sup>12</sup>	█ <sup>12</sup>	█ <sup>12</sup>	█ <sup>1</sup>
Growth		51%	34%	22%	17%	10%	10%
Ritalin LA uptake in adult ADHD population (D)		20%	30%	40%	50%	50%	50%
Ritalin LA scripts (10, 20, 30, 40 and 60 mg capsules) (E)		█ <sup>5</sup>	█ <sup>10</sup>	█ <sup>3</sup>	█ <sup>3</sup>	█ <sup>3</sup>	█ <sup>9</sup>
Lisdexamfetamine scripts displaced 20, 30, 40 60 and 70 mg capsules)		█ <sup>5</sup>	█ <sup>10</sup>	█ <sup>3</sup>	█ <sup>3</sup>	█ <sup>3</sup>	█ <sup>9</sup>
<b>Aggregate estimated financial implications dispensed Ritalin LA (10, 20, 30, 40 and 60 mg capsules)</b>							
Cost to PBS/RPBS less co-payment (\$)		█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>6</sup>
<b>Aggregate estimated financial implications of LDX (20, 30, 40 60 and 70 mg capsules)</b>							
Cost to PBS/RPBS less co-payment (\$)		█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>14</sup>	█ <sup>14</sup>	█ <sup>14</sup>
<b>Net financial implications Ritalin LA (10, 20, 30, 40 and 60 mg capsules)</b>							
Net cost to PBS/RPBS (\$)		█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>6</sup>

Source: Table 2.6, 2.7, 2.8, 2.0 and 2.10 of the submission main document and financial table workbook of the submission.

\* 2021 Services actual numbers from Jan-Sep, then █ services each month for the remaining months (Oct-Dec) consistent with the increase in monthly volumes seen since the listing expansion in Feb 2021

The redacted values correspond to the following ranges:

<sup>1</sup> 400,000 to < 500,000

<sup>2</sup> 500,000 to < 600,000

<sup>3</sup> 100,000 to < 200,000

<sup>4</sup> 700,000 to < 800,000

<sup>5</sup> 30,000 to < 40,000

<sup>6</sup> \$0 to < \$10 million

<sup>7</sup> 600,000 to < 700,000

<sup>8</sup> 800,000 to < 900,000

<sup>9</sup> 200,000 to < 300,000

<sup>10</sup> 70,000 to < 80,000

<sup>11</sup> 900,000 to < 1,000,000

<sup>12</sup> 300,000 to < 400,000

<sup>13</sup> 1,000,000 to < 2,000,000

<sup>14</sup> \$10 million to < \$20 million

- 4.16 The submission estimated a net cost saving to the PBS in Year 6 (all strengths) of listing, with a total net savings to the PBS of \$30 million to < \$40 million over the first 6 years of expanded listing.
- 4.17 The estimated net saving is significantly over-estimated when considering the effective pricing of lisdexamfetamine.

### **Sensitivity analysis**

- 4.18 The submission presented results of sensitivity analysis assuming that the source of uncertainty was the growth rates applied to LDX due to limited data available, with only 8 months of PBS statistics data available since the expanded listing came into effect.
- 4.19 The estimated use and financial implications of the sensitivity analysis are presented in Table 6. A net saving to the PBS over the first 6 years of expanded listing is estimated to be \$80 million to < \$90 million.

**Table 6: Sensitivity analysis**

	2021*	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Projected LDX PBS services for patients diagnosed at all ages</b>							
PBS Services	█ <sup>1</sup>	█ <sup>3</sup>	█ <sup>7</sup>	█ <sup>7</sup>	█ <sup>7</sup>	█ <sup>7</sup>	█ <sup>14</sup>
Growth	55%	40%	30%	25%	20%	15%	12%
<b>Projected LDX PBS services from diagnosed after 18</b>							
PBS Services	█ <sup>2</sup>	█ <sup>4</sup>	█ <sup>8</sup>	█ <sup>9</sup>	█ <sup>3</sup>	█ <sup>12</sup>	█ <sup>7</sup>
Growth		121%	59%	43%	31%	20%	14%
<b>Ritalin LA scripts and LDX scripts displaced</b>							
Ritalin LA scripts		█ <sup>5</sup>	█ <sup>2</sup>	█ <sup>4</sup>	█ <sup>8</sup>	█ <sup>8</sup>	█ <sup>1</sup>
LDX scripts displaced		█ <sup>5</sup>	█ <sup>2</sup>	█ <sup>4</sup>	█ <sup>8</sup>	█ <sup>8</sup>	█ <sup>1</sup>
<b>Net financial impact to the PBS/RPBS for Ritalin LA in the first 6 years of adult diagnosed expanded ADHD listing (published DPMQ net copay)</b>							
Ritalin LA (\$)		█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>10</sup>	█ <sup>10</sup>	█ <sup>10</sup>
LDX (\$)		█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>10</sup>	█ <sup>11</sup>	█ <sup>13</sup>	█ <sup>15</sup>
Total net financial impact PBS/RPBS (\$)		█ <sup>6</sup>	█ <sup>6</sup>	█ <sup>10</sup>	█ <sup>10</sup>	█ <sup>11</sup>	█ <sup>11</sup>

Source: Table 2.14, 2.15, 2.16, 2.17 of the submission main document.

\* 2021 Services actual numbers from Jan-Sep, then █ services each month for the remaining months (Oct-Dec) consistent with the increase in monthly volumes seen since the listing expansion in Feb 2021

The redacted values correspond to the following ranges:

- <sup>1</sup> 500,000 to < 600,000
- <sup>2</sup> 100,000 to < 200,000
- <sup>3</sup> 800,000 to < 900,000
- <sup>4</sup> 200,000 to < 300,000
- <sup>5</sup> 50,000 to < 60,000
- <sup>6</sup> \$0 to < \$10 million
- <sup>7</sup> 1,000,000 to < 2,000,000
- <sup>8</sup> 400,000 to < 500,000
- <sup>9</sup> 600,000 to < 700,000
- <sup>10</sup> \$10 million to < \$20 million
- <sup>11</sup> \$20 million to < \$30 million
- <sup>12</sup> 900,000 to < 1,000,000
- <sup>13</sup> \$30 million to < \$40 million
- <sup>14</sup> 2,000,000 to < 3,000,000
- <sup>15</sup> \$40 million to < \$50 million

4.20 As a Category 3 submission, the financial estimates analysis has not been independently evaluated.

*For more detail on PBAC's view, see section 5 PBAC outcome.*

## 5 PBAC Outcome

5.1 The PBAC recommended expanding the listing of methylphenidate (Ritalin LA) to include treatment of patients with attention deficit hyperactivity disorder (ADHD) who

are diagnosed after the age of 18. The PBAC considered that listing of Ritalin LA in the broader population would be cost-effective at a reduced price that is lower than that of LDX, and in order to achieve, at least in part, the submission's estimated cost savings in the context of anticipated market growth.

- 5.2 The PBAC noted the consumer input for this item indicating strong support for the expanded listing and considered that another treatment option for adult patients with a retrospective diagnosis of attention deficit hyperactivity disorder would be beneficial.
- 5.3 The PBAC considered the expanded listing of Ritalin LA could increase its market share relative to LDX.
- 5.4 The PBAC noted the submission proposed no change to the current price of Ritalin LA, and estimated that the weighted AEMP of Ritalin LA would be \$33.22. The PBAC also noted the submission assumed an effective AEMP of LDX which the estimated savings to the R/PBS were based on. Noting that LDX was subject to a SPA, the PBAC considered that the price of Ritalin LA should be lower than the effective LDX price in order to be cost-effective in the broader population.
- 5.5 The PBAC noted the sponsor's assumption on the market growth rates. The PBAC considered that the financial estimates would need to be revised to account for the effective price of LDX and the reduced price of Ritalin LA.
- 5.6 The PBAC noted Ritalin LA for the treatment ADHD is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 5.7 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## **6 Recommended listing**

- 6.1 Amend existing listing as follows:

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Name, Restriction, Manner of administration and form	PBS item code	Max. Qty packs	Max. Qty units	№.of Rpts	Proprietary Name and Manufacturer
METHYLPHENIDATE					
methylphenidate hydrochloride 10 mg modified release capsule, 30	3440C	1	30	5	Ritalin LA Novartis Pharmaceuticals Australia Pty Ltd
methylphenidate hydrochloride 20 mg modified release capsule, 30	2276T	1	30	5	
methylphenidate hydrochloride 30 mg modified release capsule, 30	2280B	1	30	5	
methylphenidate hydrochloride 40 mg modified release capsule, 30	2283E	1	30	5	
methylphenidate hydrochloride 60 mg modified release capsule, 30	12116Q	1	30	5	

Restriction Summary: 10829 / ToC: 10719

<b>Category/Program:</b> Section 100 Efficient Funding of Chemotherapy
<b>Prescriber type:</b> <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Restriction level:</b> <input checked="" type="checkbox"/> Authority required - Streamlined (9895)
<b>Administrative Advice:</b> <b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
<b>Administrative Advice:</b> In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only. Divided dosing is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought, repeats should only be sought for the listed target strength.
<b>Administrative Advice:</b> Care must be taken to comply with the provisions of State/Territory law when prescribing this drug
<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.
<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.
<b>Indication:</b> Attention deficit hyperactivity disorder
<b>Population criteria:</b>
Patient must be <del>or have been diagnosed</del> aged between the ages of 6 and 18 years inclusive; OR
Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.
AND
<b>Clinical criteria:</b>
Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events

	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must require continuous coverage over 8 hours
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a maximum daily dose of 80 mg with this drug
	<b>Prescribing Instructions:</b>
	A retrospective diagnosis of ADHD for the purposes of administering this restriction is: <ul style="list-style-type: none"> <li>(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and</li> <li>(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above.</li> </ul>

## 7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## 8 Sponsor's Comment

Novartis welcomes the PBAC's recommendation to expand the listing of methylphenidate to include adult patients with a retrospective diagnosis of attention deficit hyperactivity disorder (ADHD) to meet the high unmet need in this population expressed via the Consumer Comments.