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To: Nikolai Tsyganov

Assistant Secretary

Pricing and PBS Policy BR

Through: s47E(c), s47F

Director

PBS Pricing and Managed Access SN

EXECUTION OF THE DEED OF VARIATION IN RELATION TO THE DEED OF AGREEMENT FOR THE SUPPLY OF BARICITINIB (OLUMIANT®)**Purpose**

To seek your signature to agree and execute the Deed of Variation (the **Variation**) in relation to the Deed of Agreement for the supply of baricitinib (Olumiant®) between the Commonwealth and Eli Lilly Australia Pty Ltd (Eli Lilly) through the Pharmaceutical Benefits Scheme (PBS). Baricitinib is currently listed on the PBS for the treatment of rheumatoid arthritis.

Timing

A reduction in the published price of baricitinib has been proposed by Eli Lilly and is to take effect from 1 August 2024. The Variation is required to be executed prior to this date.

Special Pricing Arrangement (SPA) rebate

On 29 April 2024, Eli Lilly provided a PB11a form (**Attachment A**) reflecting an offer for a lower published price (from \$1,092.47 to \$934.00) and sought to maintain the existing effective price for baricitinib.

The effective and published prices for baricitinib from 1 August 2024 are as follows:

Form, Strength & Pricing quantity	Effective ex-manufacturer price (No change)	New Published AEMP
Tablet 2 mg, 28	s47(1)(b)	\$934.00
Tablet 4 mg, 28		\$934.00

Based on the requested published price, it has been calculated that a rebate of s47(1)(b) is required to achieve the effective price. Eli Lilly has agreed to this percentage, which will be reconciled on a monthly basis.

Details of the rebate contained in the Variation are provided at **Attachment B**.

Eli Lilly has agreed to the arrangements and has signed the Variation, which is ready for your execution, should you agree to the terms outlined in **Attachment C**.

Delegation / authority

Under Section 85E of the *National Health Act 1953* (the Act), the Minister (or his delegate) may, on behalf of the Commonwealth, enter into a deed with a provision for reimbursing the Commonwealth in relation to the provision of pharmaceutical benefits in circumstances set out in the deed.

Under the Instrument of Delegation signed by Minister Mark Butler (No 1 of 2024), your position has been delegated the authority to perform the duties under the provisions of S85E of the Act.

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Consultation

The Variation has been prepared by the Australian Government Solicitor.

Recommendation

- R1.** That you **AGREE** to the Deed of Variation in relation to the Deed of Agreement for baricitinib (Olumiant®), which gives effect to a new special pricing arrangement rebate;
- R2.** That you **EXECUTE** the Deed of Variation for baricitinib between the Commonwealth and the sponsor, Eli Lilly Australia Pty Ltd; and
- R3.** That you **NOTE** the Deed of Variation is non-binding until executed by the Delegate.

- R1.** Agreed/ Not Agreed
- R2.** Executed/ Not Executed
- R3.** Noted/ Please Discuss

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Nikolai Tsyganov
Assistant Secretary
Pricing and PBS Policy Branch
23 July 2024

Attachments:

- A:** PB11a for baricitinib
- B:** Details of the rebate contained in the Variation
- C:** Deed of Variation between the Commonwealth and Eli Lilly for baricitinib for execution (X1)

Contact officer: s47E(c), s47F

Phone: s47E(c), s47F

TRIM ref: E24-183677

Attachment A

PB11a for baricitinib



Australian Government
Department of Health

Request for Approved Ex-manufacturer Price

PB11a

(price agreed under section 85AD or determined under section 85B of the *National Health Act 1953*)

Instructions for completing a PB 11a form are available on the PBS website at <http://www.pbs.gov.au/infofindustry/useful-resources/pbs-forms>

Responsible Person (s84AF of the Act)	Eli Lilly Australia Pty Ltd	Responsible Person's Authorised Representative:
Responsible Person's Full Postal Address	Level 9, 60 Margaret Street, Sydney NSW 2000, Australia	• Name s47F
		• Telephone (Direct)
		• E-mail address

Drug: Baricitinib						Requested Effective Date: 1 August 2024			
PBS Code	Form (including strength)	Manner of Admin	Brand	Pricing Quantity	Price for Agreement or Determination (Ex-man price for pricing quantity) (AEMP)	Manu-facturer's PBS Pack Sizes	Proportional Ex-manufacturer Price for other pack sizes (PEMP)	Price Claimed by Responsible Person (Ex-Man for pack size) (where applicable)	Comment
11437Y 11442F 13689L	Tablet 2 mg	Oral	Olumiant	28	\$934.00	28	NA	NA	
11447L 11443G 13702E	Tablet 4 mg	Oral	Olumiant	28	\$934.00	28	NA	NA	Price offer subject to Special Price Arrangement s47(1)(b)

The Responsible Person requests:

A) agreement to the price in the 'Price for Agreement or Determination' column in the table above where:

- there is no Price Claimed for the pricing quantity, and the responsible person has a pack size equal to that quantity; or
- the responsible person does not have a pack size equal to the pricing quantity, and there is at least one Manufacturer's PBS Pack Size that does not have a Price Claimed;

B) a price premium/special patient contribution for pack sizes for which the Price Claimed is completed.

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Signature (Responsible Person's Authorised Representative mentioned above): _____ Date: 29 April 2024

For Department of Health completion only:	
Pricing accords with amount negotiated and recommended for agreement	Signed: _____ Date: _____