Hon Todd McClay
Minister for Trade and Investment
Government of New Zealand

27 April 2026

Dear Minister McClay,

In connection with the signing on this date of the India-New Zealand Free Trade Agreement ("Agreement"), between the Government of the Republic of India ("India") and the Government of New Zealand ("New Zealand"), I have the honour to confirm the following understanding reached during the course of the negotiation regarding Annex 7B (Pharmaceuticals), which reads as follows:

1. For the purpose of footnote 2 to paragraph 3 (Objectives) of Annex 7B (Pharmaceuticals), India advises that the following regulatory authorities are, as at the date of this letter, recognised by India as a comparable regulator:

    - Australian Therapeutic Goods Administration;
    - European Medicines Agency;
    - Health Canada;
    - United Kingdom Medicines and Healthcare Products Regulatory Agency;
    - United States Food and Drug Administration; and
    - Pharmaceuticals and Medical Devices Agency, Japan (*only for Good Manufacturing Practice (GMP) certification*).

2. Pursuant to footnote 2, India will notify any changes to this list to New Zealand in a timely manner.

3. For the purpose of footnote 2 to paragraph 3 (Objectives) of Annex 7B (Pharmaceuticals), New Zealand advises that the following regulatory authorities are, as at the date of this letter, recognised by New Zealand as a comparable regulator:

    - Australian Therapeutic Goods Administration (excluding applications approved upon appeal);
    - European Medicines Agency (centralised procedure only);
    - European Union member states (decentralised or mutual recognition procedure only);

- Health Products and Food Branch of Health Canada;
- Singapore Healthcare products Regulatory Agency;
- Swissmedic; and
- United States Food and Drug Administration.

4. Pursuant to footnote 2, New Zealand will notify any changes to this list to India in a timely manner.

I have the honour to propose that this letter and your letter in reply will constitute an understanding between our two Governments that will come into effect on the date of entry into force of the Agreement and shall be an integral part of the Agreement.

Yours sincerely,

Shri Piyush Goyal
Minister of Commerce and Industry
Government of the Republic of India

Shri Piyush Goyal
Honourable Minister of Commerce and Industry
Government of the Republic of India
Vanijya Bhawan, 16 Akbar Road
New Delhi -110001

27 April 2026

Dear Minister Goyal,

In connection with the signing on this date of the New Zealand-India Free Trade Agreement ("the Agreement") between the Government of New Zealand ("New Zealand") and the Government of the Republic of India ("India"), I have the honour to acknowledge the receipt of your letter of this date, which reads as follows:

> "*In connection with the signing on this date of the India-New Zealand Free Trade Agreement ("Agreement"), between the Government of the Republic of India ("India") and the Government of New Zealand ("New Zealand"), I have the honour to confirm the following understanding reached during the course of the negotiation regarding Annex 7B (Pharmaceuticals), which reads as follows:*
>
> 1. *For the purpose of footnote 2 to paragraph 3 (Objectives) of Annex 7B (Pharmaceuticals), India advises that the following regulatory authorities are, as at the date of this letter, recognised by India as a comparable regulator:*
>
>   - *Australian Therapeutic Goods Administration;*
>   - *European Medicines Agency;*
>   - *Health Canada;*
>   - *United Kingdom Medicines and Healthcare Products Regulatory Agency;*
>   - *United States Food and Drug Administration; and*
>   - *Pharmaceuticals and Medical Devices Agency, Japan (only for Good Manufacturing Practice (GMP) certification).*
>
> 2. *Pursuant to footnote 2, India will notify any changes to this list to New Zealand in a timely manner.*
>
> 3. *For the purpose of footnote 2 to paragraph 3 (Objectives) of Annex 7B (Pharmaceuticals), New Zealand advises that the following regulatory authorities are, as at the date of this letter, recognised by New Zealand as a comparable regulator:*

- *Australian Therapeutic Goods Administration (excluding applications approved upon appeal);*
- *European Medicines Agency (centralised procedure only);*
- *European Union member states (decentralised or mutual recognition procedure only);*
- *Health Products and Food Branch of Health Canada;*
- *Singapore Healthcare products Regulatory Agency;*
- *Swissmedic; and*
- *United States Food and Drug Administration.*

4. *Pursuant to footnote 2, New Zealand will notify any changes to this list to India in a timely manner.*

I have the honour to propose that this letter and your letter in reply will constitute an understanding between our two Governments that will come into effect on the date of entry into force of the Agreement and shall be an integral part of the Agreement."

I have the further honour to confirm that the Government of New Zealand shares this understanding and that your letter and this reply constitute an integral part of the Agreement.

Yours sincerely,

Hon Todd McClay
Minister of Trade and Investment
Government of New Zealand