



27th April 2026

Dear Todd,

In connection with the signing on this date of the India-New Zealand Free Trade 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 between India and New Zealand during the course of the negotiation regarding Annex 7A (Medical Devices):

1. For the purpose of footnote 2 to paragraph 3 (Conformity Assessment) of Annex 7A (Medical Devices), 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;
 - Pharmaceuticals and Medical Devices Agency, Japan;
 - United Kingdom Medicines and Healthcare Products Regulatory Agency; and
 - United States Food and Drug Administration.
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 (Conformity Assessment) of Annex 7A (Medical Devices), 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 Health Sciences Authority;
 - UK Medicines and Healthcare products Regulatory Agency;

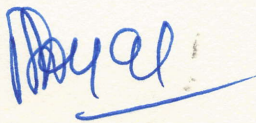
- Swissmedic; and
- United States Food and Drug Administration.

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.

With warm regards,

Sincerely,



Piyush Goyal

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