

## ANNEX 7A PHARMACEUTICALS

1. The Parties' Therapeutic Goods Regulators<sup>1</sup> shall work together to facilitate trade in human prescription medicines and medical devices.
2. To facilitate trade in human prescription medicines, including prescription generic and biosimilar medicines, and medical devices, each Party's Therapeutic Goods Regulator shall utilise, as appropriate, reports from regulatory authorities recognised by that Party's Therapeutic Goods Regulator as a comparable regulator in relation to the pre-market evaluation of products manufactured in the territory of the other Party, subject to its laws and regulations,<sup>2</sup> as amended from time to time.
3. To facilitate trade in human prescription medicines, including prescription generic and biosimilar medicines, each Party's Therapeutic Goods Regulator may utilise, as appropriate, Good Manufacturing Practice (GMP) inspection reports from regulatory authorities recognised by that Party's Therapeutic Goods Regulator as a comparable regulator in relation to the quality assessment of manufacturing facilities in the territory of the other Party, subject to its laws and regulations, as amended from time to time. This may reduce the requirement for, or duration of, in-country inspections in the territory of the other Party.
4. Neither Party shall have recourse to dispute settlement under Chapter 13 (Dispute Settlement) for any matter arising under this Annex.

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<sup>1</sup> For the purpose of this Annex "Therapeutic Goods Regulator" means for Australia, the Therapeutic Goods Administration (TGA) of Australia, or its successor; and for India, the Central Drugs Standard Control Organisation (CDSCO), or its successor.

<sup>2</sup> This is currently provided through the Comparable Overseas Regulators (CORs) pathway under the *Therapeutic Goods Act 1989* (Cth).