NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** AUSTRALIA  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  Therapeutic Goods Administration, Department of Health and Aged Care  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**  Australian WTO TBT Enquiry Point  Office of Global Trade Negotiations  Department of Foreign Affairs and Trade  Canberra ACT 0221 [tbt.enquiry@dfat.gov.au](mailto:tbt.enquiry@dfat.gov.au)  +61 2 6261 1111 |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicines |
| **5.** | **Title, number of pages and language(s) of the notified document:** Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products, 1 February 2022, PE-009- 16; (235 page(s), in English) |
| **6.** | **Description of content:** The Therapeutic Goods Administration (TGA) administers Australia's regulatory framework for the quality, safety, efficacy of therapeutic goods in Australia.  There are provisions under the *Therapeutic Goods Act 1989* (the Act) to establish Manufacturing Principles that are to be applied in the manufacture of therapeutic goods. The *Therapeutic Goods (Manufacturing Principles) Determination 2020* (the Determination) is the legislative instrument that specifies the manufacture of therapeutic goods must comply with the applicable procedures and requirements in the Pharmaceutical Inspection Co-operation Scheme (PIC/s) Guide to GMP.  As a PIC/S member, Australia is expected to adopt and enforce the latest revisions to the GMP guide to achieve international harmonisation between member countries. Adoption of the PIC/S Guide to GMP as Australia's Manufacturing Principles negates the need for Australian-specific standards, facilitates international trade and supports our international reputation.  The adoption of an internationally harmonised standard minimises regulatory burden for companies involved in the manufacture, import and export of medicines, facilitating trade and helping to ensure the availability of medicines to the Australian public. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The Determination currently specifies that the manufacture of therapeutic goods must comply with the applicable procedures and requirements in the PIC/S Guide to GMP (PE009-15, 1 May 2021) except for its Annexes 4, 5, and 14.  There is a more recent version of this document, PIC/S Guide to GMP (PE009- 16, 1 February 2022) and Australia needs to adopt this version to ensure that the rules regulating the manufacture of therapeutic goods in Australia are equivalent to those adopted by other international regulatory authorities.  Failure to adopt version 16 of the PIC/S Guide to GMP (PE-009-16) would lead to inconsistencies between domestic and international manufacturing principles which will likely lead to a disadvantage for Australian manufacturers wishing to export to overseas markets as well as reputational damage the Australian manufacturing sector and TGA's international standing.  The TGA is proposing to amend the Determination to adopt version 16 of the PIC/s Guide to GMP except for Annexes 4, 5 and 14 as the manufacturing principles and register the amended Determination on the Federal Register of Legislation in June 2024. ; Harmonization |
| **8.** | **Relevant documents:**  <https://www.tga.gov.au/resources/publication/publications/pics-guide-gmp-medicinal-products-version-16> |
| **9.** | **Proposed date of adoption:** 3 June 2024  **Proposed date of entry into force:** 3 June 2024 |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [****]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  <https://www.tga.gov.au/resources/publication/publications/pics-guide-gmp-medicinal-products-version-16> |