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  **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:**  Department of Foreign Affairs and Trade Email: [tbt.enquiry@dfat.gov.au](mailto:tbt.enquiry@dfat.gov.au) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Products regulated by the Therapeutic Goods Administration (TGA) as 'biologicals' including human tissue-based products (e.g., skin, bone, ocular, cardiovascular donor tissue); cell-based products (e.g., genetically modified cells); immunotherapy products containing genetically engineered human cells (e.g., CAR-T cells); products that comprise or contain live animal cells, tissues or organs (e.g., pancreatic islet cells isolated from pigs); autologous human cell and tissue (HCT) products (e.g., human stem cell transplants); and faecal microbiota transplant (FMT) products.; PHARMACEUTICAL PRODUCTS (HS 30) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Priority Review pathway for biologicals: feasibility, potential eligibility criteria and determination process (21 page(s), in English) |
| **6.** | **Description of content:** Australia's Therapeutic Goods Administration (TGA) is seeking feedback on a proposed priority pathway for assessment of certain novel and life-saving [biologicals](https://www.tga.gov.au/what-regulated-biological).  The proposed 'Priority Review' pathway will align with the pathway already in place for medicines and offer a faster formal assessment pathway for biologicals in certain circumstances. This will allow consumers with life-threatening diseases or seriously debilitating conditions to access these treatments in less time if the assessment results in a decision by the TGA to include the biological in the [Australian Register of Therapeutic Goods (ARTG)](https://www.tga.gov.au/australian-register-therapeutic-goods).  Australia does not currently have a formal mechanism to expedite the assessment and inclusion of biologicals in the ARTG. Depending on the feedback received, the TGA could propose to the Australian Government that a priority pathway be implemented for the pre-market assessment and registration of novel biologicals that address unmet clinical needs for Australian consumers. This would require changes to the [Therapeutic Goods Regulations 1990](https://www.legislation.gov.au/Series/F1996B00406).  The TGA is conducting a public consultation on the proposed pathway between February 2022 and March 2022 to seek feedback on:   * whether stakeholders support introduction of such a pathway * eligibility criteria for the Priority Review pathway for biologicals * the Process for determining whether a biological application meets the eligibility criteria for Priority Review (the 'Determination Process'). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objectives of the proposed Priority Review pathway are to:   * assist in achieving a faster assessment and earlier access to certain novel and life-saving biologicals that address unmet clinical needs for Australian consumers, bringing these to market faster than using standard evaluation pathways * provide timely and flexible registration processes for sponsors seeking access to the Australian market for new and novel uses of biologicals that offer substantial benefits to Australian consumers * increase alignment with other overseas regulators that offer accelerated assessment processes.   Protection of human health or safety; Harmonization |
| **8.** | **Relevant documents:**  The consultation paper on the proposed Priority Review pathway is available at <https://consultations.tga.gov.au/medicines-regulation-division/priority-review-pathway-for-biologicals>. This document outlines the proposed eligibility criteria, determination process and other considerations including fees and charges. |
| **9.** | **Proposed date of adoption:** If supported by stakeholders, the TGA could propose to the Australian Government to introduce the pathway within the next 12 months.  **Proposed date of entry into force:** If supported by stakeholders, the TGA could propose to the Australian Government to introduce the pathway within the next 12 months. |
| **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://consultations.tga.gov.au/medicines-regulation-division/priority-review-pathway-for-biologicals> |