WORLD TRADE ORGANIZATION

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Committee on Technical Barriers to Trade

Original: English

MEDICAL DEVICE REGULATION

TENTH TRIENNIAL REVIEW

Proposal from Australia

Revision

The following submission, dated 1 March 2024, is being circulated at the request of the delegation of Australia.

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1 BACKGROUND

1.1. Clear, current and effective regulation of medical devices is a necessity to ensure the health and safety of consumers. It is important each Members' right to regulate in the interest of the health and safety of their population is respected.

1.2. At the same time, interoperable regulatory systems, shared systems of nomenclature, and systems which can provide for recognition of foreign conformity assessment results can ensure the reduction of barriers to trade and avoid delays in consumer access to important, often life-saving products.

1.3. Increasingly, regulatory approvals in one country rely on the work of regulatory authorities or the regulatory frameworks in other countries. Misaligned changes to regulations can therefore disrupt trade and the supply of critical health products before alternate suppliers or regulatory arrangements can be established.

1.4. The TBT Committee has previously acknowledged the contribution of regulatory convergence in supporting the global response to the COVID-19 pandemic and this proposal would be consistent with continuing to support preparedness for future global health challenges.

2 PROPOSAL

2.1. Australia proposes a thematic session which will explore the current landscape of medical device regulation with a view to:

a. identifying relevant nexuses for the TBT Committee;

b. drawing on the expertise and experiences of relevant stakeholders, through inviting a diverse range of speakers including government regulators, the private sector and international organisations; and

c. promoting the application of regulatory approaches in accordance with core TBT principles to maximise trade and innovation outcomes.

2.2. Topics and areas of focus could include:

a. Exploration of regulatory flexibility/alternatives that leverage valid approaches used globally in respect of medical devices, including personalised medical devices and conformity assessment certification, which respond to the need for solutions that are globally harmonised, agile, mutually recognised, and consistent with risk-based approaches;

b. Reliance on consensus-based, international standards to underpin emerging approaches to personalised medical devices and medical device nomenclature, and the potential for deepening regulatory cooperation among relevant WTO Member authorities;

c. Challenges, limitations, and potential trade implications of conformity assessment frameworks in the personalised medical device context;

d. Presentations by WTO members that are currently developing approaches to medical device regulation (including those that may involve certification), with a focus on identification of best practices for facilitation of trade;

e. Presentations by industry regarding regulatory perspectives on emerging regulatory and certification approaches; and

f. The importance of transparency and procedural fairness in designing and implementing regulations, including sufficient time for industry consultation and comment.

2.3. Australia considers this proposal would be consistent with and a relevant continuation of the recommendation under Section 8.2 of the 9th Triennial Review.