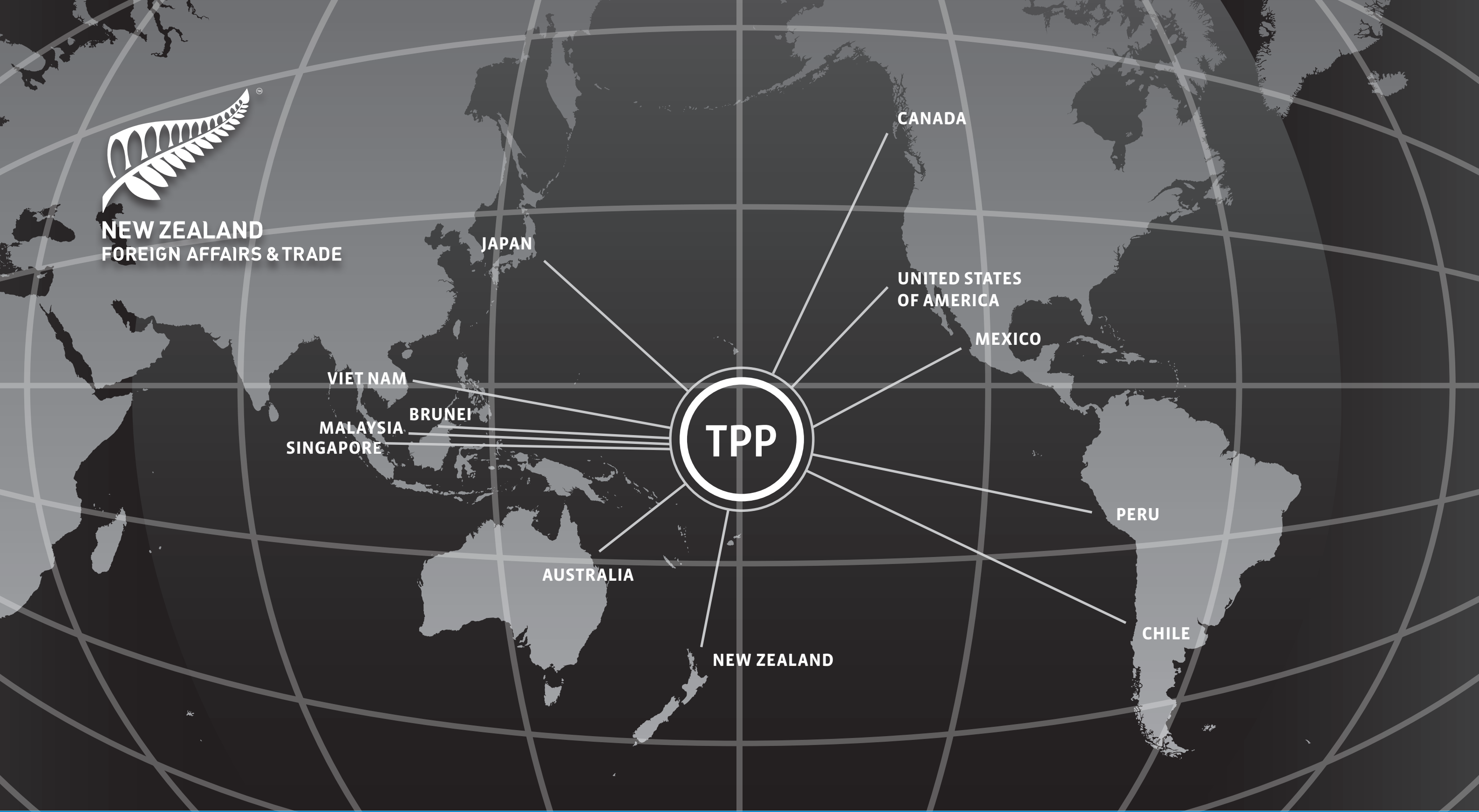

TRANS-PACIFIC partnership

PHARMACEUTICAL AND MEDICAL DEVICE PURCHASING (REIMBURSEMENT)

FACT SHEET

Overview

The Trans-Pacific Partnership (TPP) will include provisions that apply to government programmes that subsidise pharmaceuticals and medical devices. The provisions are intended to promote transparency in listing and funding processes. The outcomes reflect many existing PHARMAC practices that support transparency, but will require PHARMAC to do some new things. The provisions are annexed to the TPP Transparency chapter.

For New Zealand, the annex will apply to the Pharmaceutical Management Agency's (PHARMAC) consideration of applications to fund pharmaceuticals. While the provisions are new obligations for New Zealand, the outcomes do not change the PHARMAC model or its ability to prioritise its spending and negotiate the best price for medicines.

The annex focuses on promoting transparency in the application process and is consistent with many existing PHARMAC policies. In other areas, flexibilities have been included that accommodate current PHARMAC practice. The obligations will not change the PHARMAC model or its ability to fund, prioritise pharmaceuticals for listing for reimbursement, or

TPP will not change the PHARMAC model.

approve pharmaceutical funding. PHARMAC will continue to prioritise its funding options and negotiate with suppliers to ensure New Zealanders get the best possible health outcomes from the money the Government allocates for medicines funding.

New Zealand exporters may benefit from these provisions, to the extent New Zealand-made pharmaceuticals and medical devices are funded by healthcare authorities in other TPP countries.

What will the annex apply to?

The annex applies to listing and reimbursement programmes for pharmaceuticals and medical devices operated by 'national health care authorities'. This term is defined for each Party.

For New Zealand, 'national health care authority' is defined to mean PHARMAC.

A number of qualifications have been included which mean not all PHARMAC activities are captured. For example:

- While the annex applies to both pharmaceuticals and medical devices, New Zealand has excluded medical devices from the scope of its obligations.
- The annex only applies to formal applications, completed in accordance with PHARMAC requirements, seeking funding and listing on the *Pharmaceutical Schedule*. It does not apply to other programmes such as *Named Patient Pharmaceutical Assessment*.
- Listing and reimbursement decisions for government procurement purposes are not covered by the annex. This excludes a number of PHARMAC processes, including in respect to hospital medicines, including cancer treatments.
- As a result, a number of PHARMAC's current responsibilities such as funding hospital medicines (including cancer treatments) are excluded from the scope of New Zealand's obligations.

Key outcomes

Dispute settlement does not apply

The obligations of the annex will not be subject to either TPP's state-to-state dispute settlement mechanism nor the investor-state dispute settlement provisions of the Investment chapter. In other words, while the provisions are legally binding, TPP governments or investors will not be able to bring formal dispute settlement proceedings if they have concerns about another Party's approach to implementation of the annex.

Agreed principles

TPP Parties have agreed the annex does not affect the right of governments to determine health expenditure priorities.

Other general principles are also included such as the importance of protecting and promoting public health and research and development, the promotion of timely and affordable access to pharmaceuticals and medical devices, and the importance of appropriately recognising the value of these products. There are no specific obligations attached to these principles; TPP Parties have simply acknowledged their 'importance'.

Commitment to consider funding applications within a specified period of time

TPP Parties have agreed to ensure that consideration of all formal applications is completed in a specified timeframe. The timeframe can be determined by each Party.

An exception to this obligation has been included that allows this timeframe to be extended provided the reason for the extension is disclosed. This exception is noteworthy given PHARMAC may assess applications over multiple budget cycles or defer a final decision until funding is available.

A review mechanism

TPP Parties have agreed to make available a review mechanism that applicants can elect to use if their application for funding is declined. While PHARMAC processes and decisions are subject to judicial review in New Zealand, and a review process is already in place for *Named Patient Pharmaceutical Assessment* applications, PHARMAC does not currently offer a specific review process for applications that have been declined for listing on the *Pharmaceutical Schedule*.

The obligation in TPP to implement a review mechanism includes a number of flexibilities:The review is not an appeals process and there is no requirement to change a decision.

- An internal review process is sufficient to meet the obligation. In other words, the decision maker, PHARMAC, may undertake the review.
- Broad freedom to design and implement the review process, including drawing from existing practice and design principles used internationally such as cost-recovery.
- When reviewing an application, the reviewer does not need to consider assessments related to other proposals for funding. This means that PHARMAC's process of prioritising all applications is not subject to review. This supports PHARMAC's cost effective and confidential negotiations with pharmaceutical suppliers.
- Only one review per application is required, with flexibility to decide at what point that review might be made available.

Publication and consultation

The annex includes a number of provisions that promote transparency and consultation. These reflect existing PHARMAC processes, such as the publication of significant amounts of material on PHARMAC's website, the processes it uses to engage suppliers throughout the application process, and the information published on decisions. The provisions do not require new specific processes to be put in place, but PHARMAC may decide to implement new approaches that have been under consideration and will support the continued operation of an efficient and effective system.

TPP Parties have also agreed to a government-to-government mechanism to facilitate dialogue and mutual understanding on the issues covered by the annex.

Implications

Implementing these provisions is expected to involve up to $4.5 million in one-off establishment costs for PHARMAC, and $2.2 million per year in operating costs.