Anne Harris
Managing Director
Pfizer Australia and New Zealand
Level 15-18
151 Clarence Street
Sydney 2000

Committee Secretariat
Health Committee
Parliament Buildings
Wellington
Health@parliament.govt.nz

Dear Sir/Madam

Re: Therapeutic Products Bill NZ

Thank you for the opportunity to provide comment on the Therapeutic Products Bill.

Pfizer New Zealand is one of the nation's leading providers of prescription medicines. We manufacture medicines and vaccines that thousands of New Zealanders use every day to live longer, healthier and more productive lives. Pfizer has a proud history in New Zealand. This year marks the company's 62nd anniversary of operations here. Throughout this period, we have taken great pride in ensuring patients can access new and innovative medicines and vaccines that are being used to treat and help prevent some of the most serious health conditions of our time. We are especially proud to be partnering with the New Zealand Government as the principal supplier of safe and effective COVID-19 vaccines and antiviral treatments across the country.

The response to the COVID-19 pandemic has demonstrated that a healthy New Zealand, leads to a healthy economy and it is timely that the Government is replacing the Medicines Act and taking steps to ensure New Zealanders have timely access to the latest safe and effective, medicines and vaccines. As we look to embrace the lessons learnt from COVID-19, now is the right time to assess whether we have the appropriate systems in place to deliver the best healthcare outcomes in this rapidly changing environment.

Pfizer New Zealand supports the purpose of the new Therapeutic Products Bill and understands the need for the Bill to be less prescriptive than the current Medicines Act. We also welcome the guiding principles of delivering a regulatory process that is independent, transparent, and accountable, that supports 'timely access to products, open and well-functioning markets, and innovation' and that aligns with international best practice. We are wholly supportive of establishing a regulatory environment that is predictable and transparent, with fair decision making, whilst maintaining flexibility in overall regulatory processes.

However, there are aspects of the legislation that extend beyond these guiding principles and may hinder efforts to bring forward safe and effective medicines to NZ in a timely manner. Pfizer hopes this consultation process and feedback from stakeholders will lead to modifications to the legislation that will address some of these issues prior to a second reading.

Pfizer is an active member of Medicines New Zealand, and we support their detailed submission and recommendations to the Committee.

Yours sincerely,

Anne Harris
Managing Director, Pfizer Australia and New Zealand

Therapeutic Products Bill NZ (2023)

Support for Medicines New Zealand submission to the Committee

Pfizer is an active member of Medicines New Zealand (MNZ), and we support their detailed submission to the Committee. We note MNZ lead their submission by stating that they cannot support the Bill in its current form.

In their submission MNZ outline concerns in the manner in which the Bill is drafted that may impact on the ability of the health system to function effectively and equitably in the provision of quality, safe and effective medicines and vaccines. They also call for the Bill to be more explicit in committing to expedited, timely review of medicines and vaccines where appropriate, to ensure that manufacturers have predictability and certainty in the regulatory review process, and to ensure the process in NZ is on par with other comparable jurisdictions.

Pfizer supports MNZ's comprehensive recommendations to the Committee to address some of these issues including their request for more fulsome consultation and consideration of the legislation. The Medicines Act is more than 40 years old and the way in medicines are researched, manufactured, distributed and prescribed is vastly different today than it was in 1981. Updating the Medicines Act is a landmark opportunity to consider this evolving landscape and to future proof the medicines ecosystem in NZ for years to come. If more time is needed to properly consider all aspects of the legislation, then Pfizer supports additional consultation.

Pfizer also agrees with MNZ that a predictable operating environment with established timeframes does provide greater certainty for manufacturers to factor into their regulatory approval considerations and global stock requirements. This predictability should extend to when decisions will be made by the regulator and when further input will be required. Pfizer, like many other manufacturers, must consider how to best allocate resources within our global organisation. Having certainty for review timeframes will not only benefit the manufacturer, but the regulator as well, as companies will be better prepared to respond to submission milestones. Establishing a clear, transparent timeframe for regulatory review and maintaining this standard, would be in keeping with the guiding principles of the Therapeutic Products Bill.

Items in the legislation for clarification

1. Enforcement and Penalties

Pfizer is concerned with the proposal that if a company contravenes a provision of the Act, a senior manager of the company is taken to have also contravened the provision unless in defence, they did not know and could not reasonably be expected to have known of the contravention or took all reasonable steps to ensure the conduct did not occur. This shifts significant liability to an individual and places the burden of defence on senior managers. The apportionment of liability introduced by this section should be revised.

2. Sponsor responsibilities, contractual relationship with responsible manufacturers

Pfizer assumes that the intent of this requirement is to facilitate the supply of relevant manufacturing information to the New Zealand based responsible person for supply to the Regulator as required.

However, the Bill lacks clarity on what is meant by a "contractual relationship" and the nature of such a relationship. We believe that this contractual relationship is more relevant to third party manufacturers rather than manufacturing sites that are owned by the parent company or global affiliate of the New Zealand Sponsor. Accordingly, we do not believe that this requirement should apply where the responsible manufacturer is a manufacturing site owned by the parent company or a global affiliate of the New Zealand Sponsor.

3. Responsible person

In relation to the nomination of a **"Responsible person"** for oversight of the activities of licensees as set out in **Part 5** of the Bill, this raises a similar issue of attribution of liability between the body corporate and the 'responsible person', and to what extent would a breach warrant a fine to the company or imprisonment of an individual or both.

Whilst Pfizer is supportive of risk proportionate regulatory processes, it seems counter intuitive to the purpose of the Bill to introduce significant regulatory burden on individuals in addition that placed on the New Zealand sponsor.

4. Maintaining direct to consumer advertising (DTCA) will help to ensure balanced, factual information for patients and clinicians

Pfizer supports the continued permission of direct-to-consumer advertising (DTCA) of all medicines and vaccines, with the exception of controlled drugs. DTCA raises the awareness of medical conditions, informs consumers about the benefits and risks of medicines, and motivates people to search for information about health conditions and treatments (including non-medical approaches) and to review discuss prevention, diagnosis, treatment, and wellness information with their health care professional.[i] [ii]

DTCA also plays a significant part in supplementing public health strategies, which is particularly valuable to ensure that important health information is communicated in a widespread and open way to avoid disparity in the distribution to minority patient groups or communities.

The digital health revolution is leading to the fragmentation of health information. Increasingly consumers are seeking out their own information before consulting health professionals and making decisions on their treatment pathways based on this initial advice. Health literacy is more important now than ever. So too is promoting trusted, accurate and reliable sources of information. DTCA undergoes rigorous checks and balances to maintain compliance and can play and important role in this regard.

The current regulatory regime for medical advertising in NZ works well. DTCA is performed in a responsible manner by Pfizer. Pfizer ensures all advertisements are balanced and do not contain misleading information through both internal checks, via Pfizer New Zealand's knowledgeable, expert group of medical and scientific professionals, and external checks through the Therapeutic Advertising Pre-vetting

Service (TAPS). Pfizer also notes the submission from the Association of New Zealand Advertisers Inc. to the Committee which demonstrates that between 2017 and 2021 there has been strong compliance from the medicines industry in relation to DTCA. In fact, during that time the Association received more than 4600 complaints across all advertising and less than 1% of these complaints related to direct-to-consumer medicines advertisements.

One issue of concern in the draft legislation is the broad definition of what constitutes an 'advertisement' in **Section 193** and **Section 194**. "Advertisement" is broadly defined to cover "a communication made for the purpose of promoting the product", whereas the definition of "advertisement" in the Medicines Act applies to communications which "promote the sale of medicines". The broader concept in the Bill may capture communications about a therapeutic product, including those that are intended for general public awareness of health conditions and the available treatments. Other examples of communications that could fall under the "advertisement" definition in the Bill include, patient education and disease awareness campaigns, medical literature (e.g. journal articles and treatment guidelines), individual fundraising activities related to a particular treatment, patient advocacy activities (e.g. materials developed by patient advocacy groups in collaboration with a sponsor company), as well as medical education content created by a sponsor company aimed at healthcare professionals.

All of the above communications will be subject to the advertisement requirements and prohibitions under **Section 194.** The rationale behind the broadening of the definition of "advertisement" in the Bill is unclear. Pfizer believes that the existing definition of **"advertisement"** as in the Medicines Act 1981 should be retained or the scope of the definition in the Bill should be qualified.

It is important to note, that patients cannot obtain prescription medicines without consulting a healthcare professional (HCP) in New Zealand. DTCA of prescription medicines does not preclude patients' interaction with their HCP prior to starting a treatment, which allows the HCP adequately diagnose and assess the suitability of a treatment for the patient.

Furthermore, Pfizer believes that a strong Regulator with the powers envisaged in **Section 194**, in combination with the powers in **Section 219**, will ensure the benefits derived from DTCA are achieved. A strong Regulator, in combination with the Therapeutic Advertising Pre-vetting Service (TAPS), will also enhance the confidence of the public and healthcare professionals that any advertising is accurate, fair, balanced and in the best interests of the New Zealand public.

5. Shortage and Discontinuation of Reportable Products

Section 145 and **Section 146** of the Bill sets out the requirement for the sponsor of a reportable product to notify the Regulator of a likely shortage of the product in the next six months, and if the sponsor intends to stop supplying the product. A mandatory reporting scheme for medicine shortages and permanent discontinuations of supply was introduced in Australia by the TGA in 2019. We submit that the New Zealand reporting requirements should, wherever possible, be aligned with those established by the TGA medicines shortage reporting framework in Australia.[iii]

Among the differences to the proposed process for New Zealand, under Section

145(2)(a) of the Bill, the Regulator must be notified within 4 days after the sponsor becomes aware of the likely shortage of a critical needs product. This timeframe would be challenging and impractical in situations where a sponsor becomes aware of a likely shortage on a Thursday or Friday, for example. A possible solution may be to amend this timeframe to 4 working days or alternatively implement the Australian approach, which is within 2 working days.

There is also considerable administrative burden on both the industry and the Regulator in the implementation of such reporting requirements. It is unclear whether the notification will be made electronically (e.g. via an online portal created by the Regulator for this purpose) or manually by email and/or a form. Ideally reporting should be electronic and align with the TGA's technical requirements, to facilitate efficient adoption of reporting to the regulator. The administrative burden of manual processing may cause delays which defeats the endeavour of timely reporting at the Sponsor's end.

6. Import or Supply of product that does not have a New Zealand market authorisation

The current drafting of Section 155 raises questions around the timeliness of licence/permit process and whether this administrative burden will have an impact on patient access in certain situations, such as a shortage. Adding, time, cost and complexity to obtaining the licence may make it commercially unviable to supply low volume medicines to patients in response to such a shortage.

It is also unclear whether the current reporting requirements under Section 29 of the Medicines Act 1981 will continue to exist as part of the condition of the licence. Schedule 1 Part 1 Subpart 3 of the Bill states provides for a 6-month grace period for the supply of medicine under Section 29 of the Medicines Act 1981 after commencement of the new Act. Details of the process, timelines for the licence/permit and reporting requirements will presumably be incorporated into the Rules (secondary legislation), however it is uncertain whether the Rules will be finalised within 6 months of commencement of the new Act.

7. Cost recovery and ongoing resourcing of Medsafe

Pfizer acknowledges the basis for cost recovery as it relates to the activities of and services provided by the regulator and is committed to working towards improved processes that will benefit New Zealanders accessing the wide range of health technologies assessed by the regulator.

Any consideration of cost recovery must be accompanied by efficiencies and adoption of clear, accountable processes. Pfizer is aligned with MNZ who have stated in their submission that they support cost recovery provided it is on fair and reasonable grounds. Government funding should support the administration of the regulatory regime with industry-based cost recovery being calculated based on the actual costs for the activities undertaken and services delivered.

[i] Jessica T. DeFrank, Nancy D. Berkman, Leila Kahwati, Katherine Cullen, Kathryn J. Aikin & Helen W. Sullivan (2020) Direct-to-Consumer Advertising of Prescription Drugs and the Patient–Prescriber Encounter: A Systematic Review, Health Communication, 35:6, 739-746

[ii] https://www.fda.gov/drugs/information-consumers-and-patients-drugs/impact-direct-consumer-advertising and https://www.kff.org/wp-content/uploads/2013/01/understanding-the-effects-of-direct-to-consumer-prescription-drug-advertising-report.pdf)

[iii] Reporting medicine shortages and discontinuations in Australia - Guidance for sponsors (tga.gov.au)