Health & Pharmaceutical Landscape of New Zealand

A ROADMAP FOR INDIAN PHARMA COMPANIES

Research conducted by:

India New Zealand Business Council

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New Zealand

MAKE IN INDIA

High Commission Of India
Wellington, New Zealand

Health & Pharmaceutical Landscape of New Zealand

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Foreword

H.E. Mr. Muktesh Pardeshi

High Commissioner of India to New Zealand

I am pleased to present a business manual *Health & Pharmaceutical Landscape of New Zealand: A Roadmap for Indian Pharma Companies* which has been jointly put together by the High Commission of India to New Zealand with the valuable collaboration of India-New Zealand Business Council as a research partner.

In the year 2021, New Zealand imported NZ$ 91.03 million of pharmaceutical products from India, representing 2.3% of total imports of pharmaceutical products. There is a huge potential for growth in bilateral trade in the pharmaceutical sector considering the fact that India enjoys an important position in the global supply. India is the largest provider of generic drugs globally. Indian pharmaceutical sector supplies over 50% of the global demand for various vaccines. Globally, India ranks 3rd in terms of pharmaceutical production by volume and 14th by value.

The New Zealand pharma landscape is regulated under the regime of Pharmac. Not much is known about it in India. This manual is a sincere effort to put together relevant details relating to steps to be taken for exporting medicines to New Zealand and listing of relevant organizations. The report also gives important contact details of key stakeholders in New Zealand. This publication is an all-in-one guide for all stakeholders in the Pharma sector in India who desire to trade with New Zealand.

I would like to thank our knowledge partner- India-New Zealand Business Council for their outstanding work. My special thanks to Mr. Gaurav Gupta for his painstaking research and compilation. Thanks are also due to the officials in the Commercial Section of the High Commission, especially to Mr. Manoj Sahu, Commercial Representative, Mr. Anubhav Varshney, Commercial Assistant and Ms. Kiren Rawat, Marketing Assistant for their support in bringing out this timely report.

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Foreword

Mr. Earl Rattray

Chair, India New Zealand Business Council

India New Zealand Business Council and the Indian High Commission are proud to present to you our latest publication on the Health and Pharmaceutical Landscape of New Zealand.

This report emerged out of many conversations from our event late last year, held in the midst of a growing need for collaborations between countries to put an end to a pandemic unlike any our generation had ever seen. Thankfully, we are now in a much better position in recovering from this crisis. It is a testament to the incredible resilience everyone has collectively shown in the face of a crisis like a few others.

It has been a time of profound change; but the nature and shape of that change is not yet fully apparent. As we emerge from the Covid era, the continued need for collaboration between nations to provide a sustainable and healthy future for the world is very evident.

Being the Pharmaceutical capital of the world, India led the charge in providing over 66 million doses to nearly 100 countries, while immunising its own population of over 1 billion. New Zealand is one of the greatest success stories in managing the pandemic, with a low mortality and an economy that's slowly heading towards an early recovery. Both nations are turning a leaf over into a new era – an era where collaborations to ensure equitable access to healthcare is of paramount importance.

Into this era, India New Zealand Business Council is pleased to launch this report that provides a comprehensive outlook of the New Zealand health and pharmaceutical sector.

New Zealand's pharmaceutical sector is unique and highly regulated one. While the buying of medicines and related products is done by the government, the management is looked after by Pharmac, a New Zealand government agency that decides which medicines are funded in New Zealand.

With this report, the council aims to shed light on these different aspects of this industry including providing a pathway to export to NZ. Our primary objective is to help increase collaboration between Indian pharmaceutical companies and distribution agencies of NZ.

We are grateful to the Indian High Commission and to the Indian High Commissioner to New Zealand, Muktesh Pardeshi for his leadership and vision in conceptualising this report. We value the trust placed in the India New Zealand Business Council to develop this report. We would also like to extend our appreciation to industry professionals and organisations who have participated and guided us in this research.

The Council trusts that the insights provided in this report guide businesses to make informed decisions about the New Zealand pharmaceutical sector.

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Disclaimer: This report is a collection of primary and secondary data, available through research and interviews. INZBC and the Indian High Commission, NZ, does not take responsibility of any business decisions taken, on the basis of this report. The objective of this report is to form a broad view of the Pharma Sector in New Zealand. Companies wishing to invest in New Zealand, are encouraged to do their own research.

Chapter 1: Overview of the sector

New Zealand Environment

New Zealand has a unique environment for publicly funding medicines. It's model for medicine funding is the only one in the world that operates with a capped budget.

The simplified process for a modern medicine, publicly available in New Zealand is as follows.

1. A medicines company [NZ based sponsor] submits a new medicine application to Medsafe

2. Medsafe checks that the medicine meets safety requirements and decides it can be used in New Zealand

3. A medicines company submits a medicine funding application to PHARMAC

4. PHARMAC's Pharmacology & Therapeutics Advisory Committee (PTAC) of doctors and specialists assess the funding application

5. PTAC recommend to PHARMAC whether to fund the medicine and they give the medicine a priority rating

6. PHARMAC then independently analyse the medicine against its factors for consideration

7. PHARMAC decides either to publicly fund the medicine ("list" the medicine) or consider the medicine for possible future funding ("rank" the medicine)

If the medicine funding application is successful, on average the decision process takes 4.15 years. Otherwise, medicines recommended by PTAC sit on the waiting list which currently has over 100 medicines waiting for funding – some have been waiting more than 10 years and counting (one medicine for 15 years).

Companies do have the option to distribute in the private retail market as well.

Medicines New Zealand Strategy

New Zealand government has defined three main outcomes for medicines in New Zealand:

Access: New Zealanders have access to the medicines they need, regardless of ethnicity, location or wealth.

Optimal use: medicines used to their best effect

Quality: medicines that are safe and effective.

PHARMAC focuses on access to and the best use of medicines. They decide which medicines will be government funded. Quality is primarily the role of other organisations, such as Medsafe.

Source: [1] Pharmac | Our place in the health system

Main agencies involved in managing the sector

The main 3 agencies involved in this sector are:

Medsafe NZ: checks that the medicine meets safety requirements and decides it can be used in New Zealand

Pharmac NZ: decide either to publicly fund the medicine ("list" the medicine) or consider the medicine for possible future funding ("rank" the medicine)

Medicines NZ: advocates to improve access to modern medicines for New Zealand patients. Medicines New Zealand is an industry association whose members are engaged in the research, development, manufacture and marketing of modern prescription medicines.

Other agencies/stakeholders in the sector:

The Minister of Health

The Minister takes responsibility for PHARMAC's performance.

Expectations of PHARMAC are set by the Minister who is also involved in appointing the PHARMAC Board.

The PHARMAC Board provides reports and briefings regularly to the Minister of Health.

Ministry of Health

PHARMAC works with the Ministry of Health, which acts on behalf of the Minister, to track its performance. PHARMAC takes part in the Ministry of Health's Health Sector Forum. The aim is to build understanding of health system priorities amongst health agencies and provide leadership to the sector in key areas.

Parliament and Members of Parliament

As a Crown entity, Parliament holds PHARMAC to account for their actions. PHARMAC helps the Minister respond to Parliamentary Questions (questions asked about their operations by Members of Parliament). Their performance is also scrutinised by Parliament's Health Select Committee. PHARMAC also assists MPs with queries from their local constituents.

District Health Boards (DHBs)

DHBs hold the funding for most publicly financed health services, including the Combined Pharmaceutical Budget (CPB) and hospital medical devices. PHARMAC's Memorandum of Understanding with the DHBs provides a sound basis for working together over time.

Sector Operations Group

Sector Operations Group is the Ministry's claims processing unit. It pays pharmacists for the subsidised medicines people get from their community pharmacy. It also processes Special Authority applications for medicines with specific criteria that must be met before they are funded. PHARMAC decides what the criteria are and the Ministry checks that applicants meet the criteria.

[More information on Special Authorities: see Further Reading 1]

New Zealand Health Partnerships Ltd

This multi-parent Crown subsidiary is led, supported, and owned by New Zealand's 20 District Health Boards (DHBs). Together they identify and build services to benefit the New Zealand health sector.

New Zealand Health Partnerships web address is www.nzhealthpartnerships.co.nz(external link)

CARM

The Centre for Adverse Reactions Monitoring (CARM) in Dunedin is New Zealand's national monitoring centre for adverse reactions. These include the side effects of a medication or surgery. It collects and evaluates reports of adverse reactions to medicines, vaccines, herbal products and dietary supplements from health professionals in New Zealand. Reports are then provided to Medsafe. CARM's web address for reporting is https://nzphvc.otago.ac.nz/reporting/(external link) , and is part of the NZ Pharmacovigilance Centre website.

Clinicians and other prescribers

Prescribers include general practitioners, specialists, and nurses. They put the Pharmaceutical Schedule into practice. They refer to it on a regular basis to determine which subsidised medicines are available for their patients.

PHARMAC also seeks clinical advice from PTAC (Pharmacology and Therapeutics Advisory Committee) and their various sub-committees as well as special access panels, health professionals, PHARMAC staff and through consultations.

Pharmacists

In the community, pharmacists dispense prescriptions and advise patients on how and when to use the prescribed medicine. In the hospital, pharmacists play a vital role in ensuring the funded treatments are available as prescribed. As with prescribers, PHARMAC relies on feedback from pharmacists on the practicality of Schedule changes.

Health professional groups

Professional associations for doctors, pharmacists, nurses and other health professionals such as clinical engineers, provide an important perspective on medicine funding issues and PHARMAC's approach to hospital medical devices management. PHARMAC meets with such groups and seeks their input through the consultation processes. Working alongside these organisations, they develop activities to manage changes in medicines, improve access to and encourage responsible use of pharmaceuticals.

Consumer and patient groups

The decisions PHARMAC makes impact on almost all New Zealanders, so it is important that the impact of those decisions on patients and consumers is well thought through. PHARMAC is in regular contact with patient and consumer groups and welcome feedback on medicine funding, their devices work, or other issues. To ensure they get appropriate consumer input to operations, they take advice from the Consumer Advisory Committee on engagement plans and practices.

Pharmaceutical companies

PHARMAC relies on pharmaceutical companies to provide medicines for New Zealanders. In most cases, when PHARMAC funds a medicine they agree on a supply contract with the company to ensure they continue to supply the contracted medicines.

Pharmaceutical companies are also required to provide information on; how a medicine or medical device works, its interactions and side effects, as well as all the information PHARMAC needs to assess the medicine for funding using the Factors for Consideration. This information is available through Medsafe.

Regulatory Consultants & Sponsors:

Regulatory consultants are independent individuals or agencies, who are authorised to register new drugs in New Zealand, to Medsafe.

[A complete list of such regulators is given later in this report in Chapter 9: Important Industry Contacts]

Sponsors are companies that are registered in New Zealand and support marketing & distribution of medicines in the local market. They may have the capacity for medicine registration, distribution, warehousing, testing, marketing, etc.

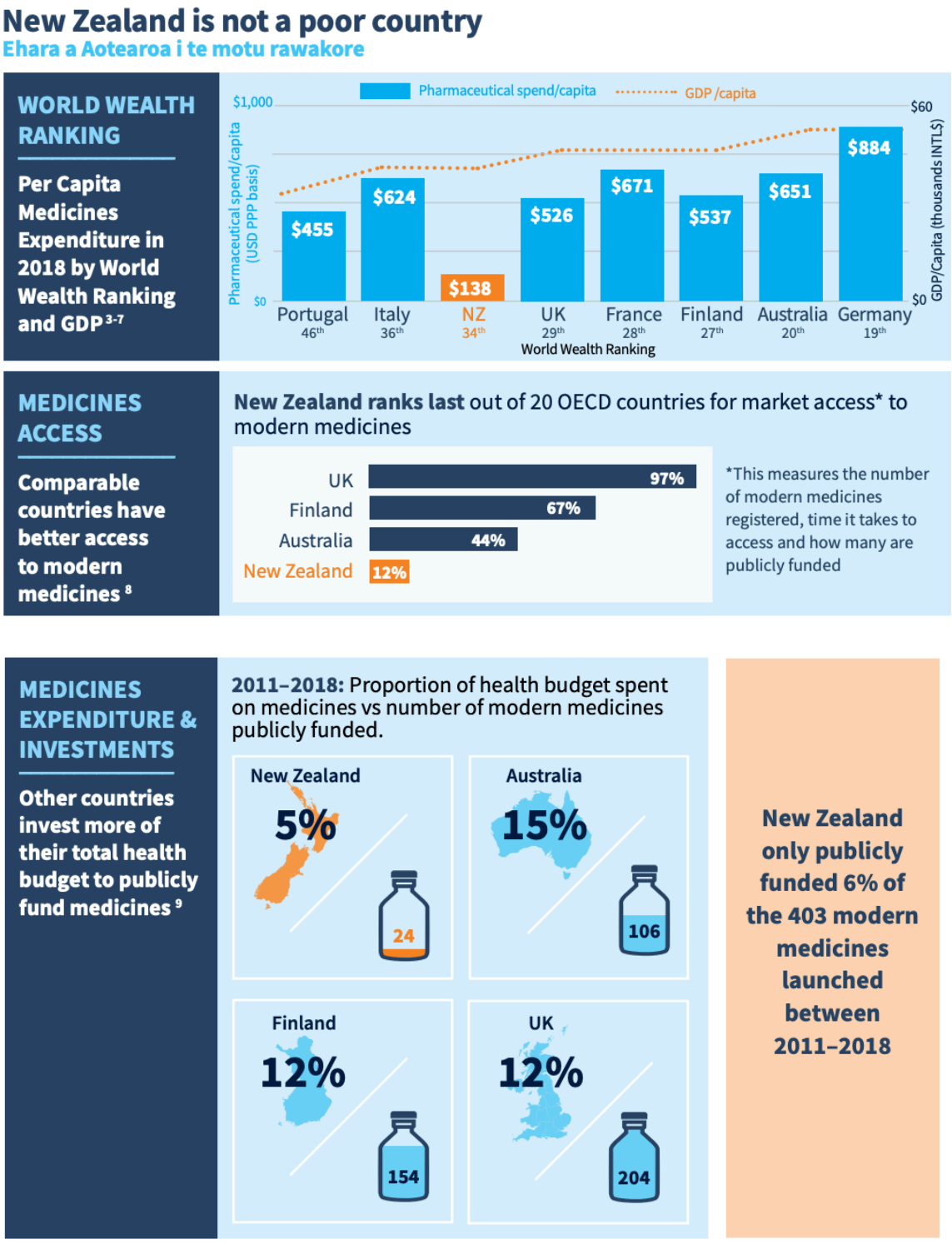
Sponsors will be the first port of call for any exporter from overseas.

[For more details read Chapter 2: Understanding the export journey]

General issues faced by this sector in New Zealand: A Snap Shot

Some highlights from Medicines NZ report 2020/21:

- New Zealand ranks last out of 20 OECD countries for market access* to modern medicines.
- Three times more modern medicines were publicly funded in Australia between 2011 and 2017



Source: [2] Medicines Landscape 2020/21

PROBLEM

While the total health budget has increased, the medicines budget has not kept pace with population growth and inflation.[2]

New Zealand's medicines budget has been significantly underfunded

2007 → -0.3% → 2018

Between 2007 and 2018 the medicines budget shrank in real terms by 0.3%.

$80 investment per person per year is required to return medicines funding to the equivalent of **2007 levels**

PROBLEM

The existence of a waiting list of more than 100 recommended medicines is evidence that New Zealand's budget levels require review. Without a review the waiting list is likely to continue to exist — if not grow.[3]

The medicines waiting list continues to grow

Average waiting time

4.75 years

and counting

Includes **110** new listings in areas such as:

- **Cancer: 17**
- **Diabetes: 11**
- **Cardiovascular: 8**
- **Rare disorders: 11**
- **Mental health: 6**

How are New Zealanders doing?

CANCER

Survival rates are worse for New Zealand patients[1-4]

Median survival for advanced breast cancer patients

16 months New Zealand

32+ months Global

Cancer survival rates are worse for Māori than non-Māori

Māori women

1.5x more likely to die from breast cancer

2.5x more likely to die from cervical cancer

4x more likely to die from lung cancer

Māori men

3x more likely to die from lung cancer

3.5x more likely to die from liver cancer

1.5x more likely to die from prostate cancer

One of the contributing factors is better access to medicines overseas.

Between 2011 and 2018 **New Zealand publicly funded only 7 of the 90 modern cancer medicines** launched in the OECD in that period

CARDIOVASCULAR DISEASE

Cardiovascular disease affects Māori more frequently than non-Māori [4-6]

170,000
New Zealanders living with cardiovascular disease

Māori 2x more likely to die than non-Māori

Māori 1.5x more likely to be hospitalised than non-Māori

Only 1 modern medicine to treat cardiovascular disease was publicly funded between 2011-2018 in New Zealand **out of the 22 medicines** launched in the OECD

DIABETES

Diabetes impacts our ethnic communities more significantly [4,7,8]

Currently **250,000+** **New Zealanders with diabetes**

Nearly **40** people diagnosed every day

1 in 9 Pacific Islanders
1 in 9 Indo-Asian

1 in 18 Māori

1 in 22 European/other

Between 2011 and 2018 **New Zealand did not fund any of the 34 modern medicines to treat diabetes** that were launched in the OECD in that period.

ARTHRITIS

Arthritis is a leading cause of disability and loss of wellbeing [4,9]

Currently **670,000** with arthritis in New Zealand

Expected to rise to **1 million** by 2040

Māori men 1.4x more likely to have arthritis than non-Māori men

Between 2011 and 2018 **New Zealand did not fund any of the modern medicines for arthritis** that other countries publicly fund

RARE DISEASES

Patients with Rare Diseases and their family face a lifetime of inequity [4,12,13]

1 in 17
New Zealanders living with a **rare disease**

1 in 3
New Zealand **rare disease patients** are often **unhappy and depressed**

2 v **36**
Only **2** modern medicines to treat rare diseases publicly funded between 2011–2018 in NZ out of **36** launched in the OECD

MENTAL HEALTH

Brand switches can impact patients [4,10,11]

Changing the brand of funded antidepressant medicines

$5 million per year saved on the cost of the medicine

But:

- **142 side effects reports**
- **1 suicide attempt reported**

1 suicide = $5.6m

The impact of 1 suicide is estimated to cost New Zealand $5.6 million

Between 2011 and 2018 **New Zealand did not publicly fund any of the modern medicines for mental health** launched in the OECD in that period

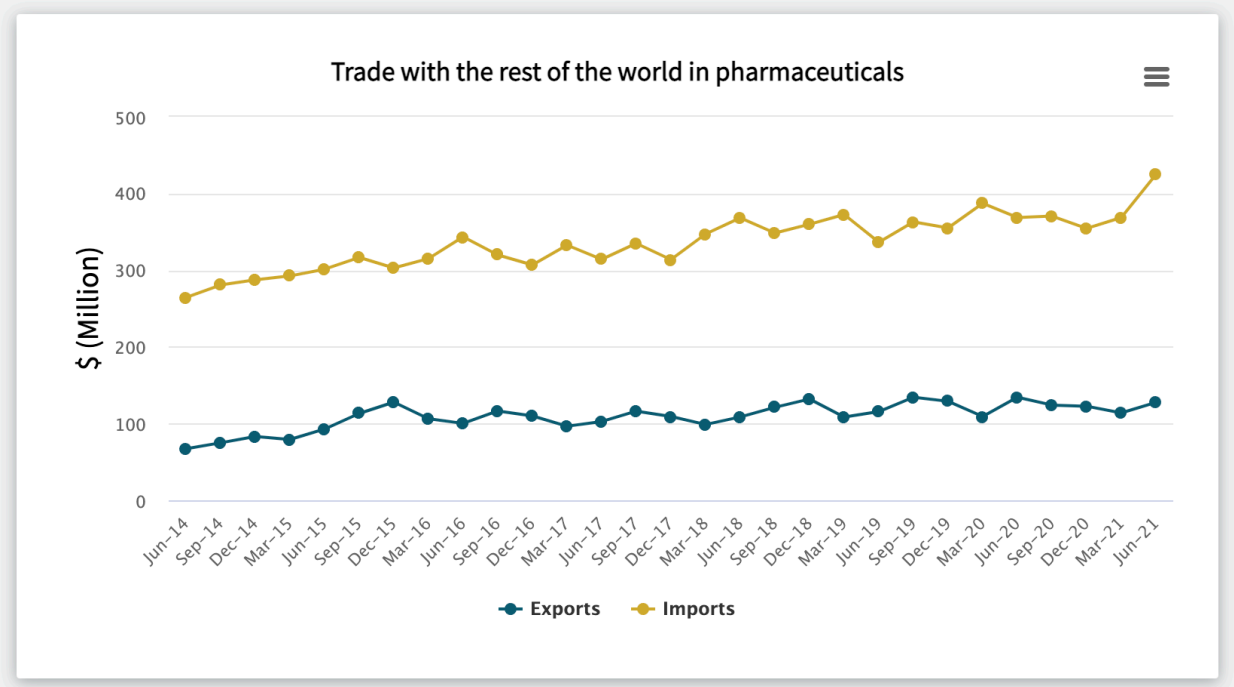
"Generics do not always lead to the anticipated monetary savings and also raise compliance issues"

–Desmarais, Beauclair & Margolese

Industry Trade in Figures

In the June 2021 quarter New Zealand exported $127.64 million of pharmaceuticals to the rest of the world and imported $424.59 million, representing a trade balance of $-296.95 million and a total trade value of $552.23 million.

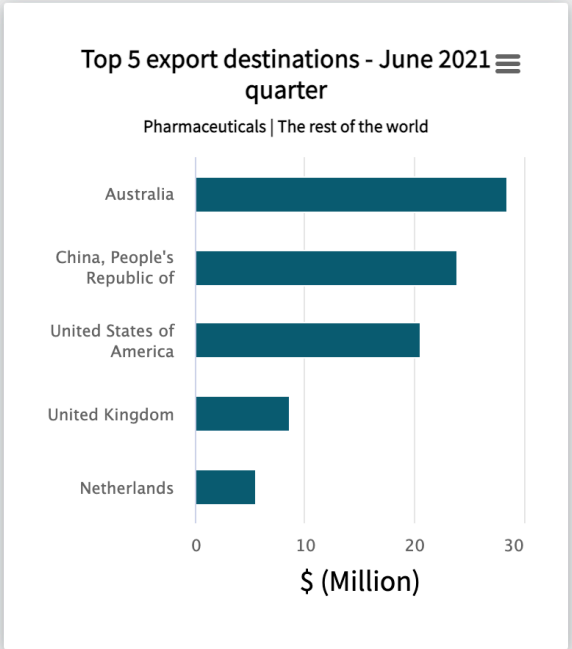
This represented 0.7% of all goods exports to the rest of the world and 2.8% of imports.



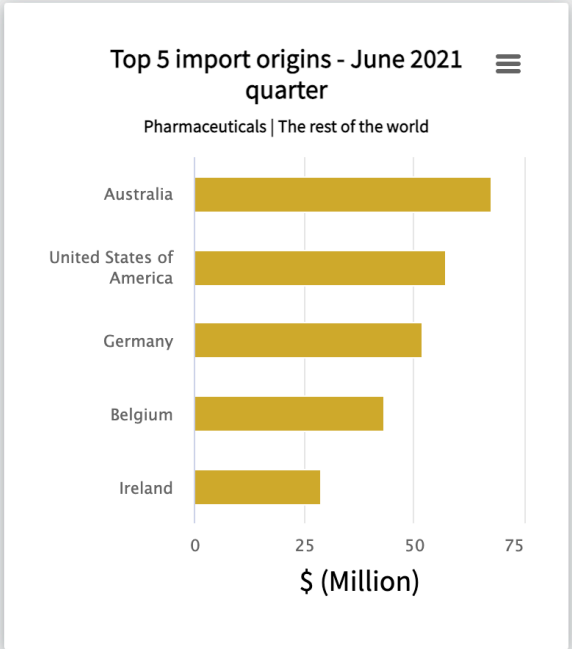
Top 5 countries for export-import of pharmaceuticals

[As on June 2021 quarter]

Exports



Imports

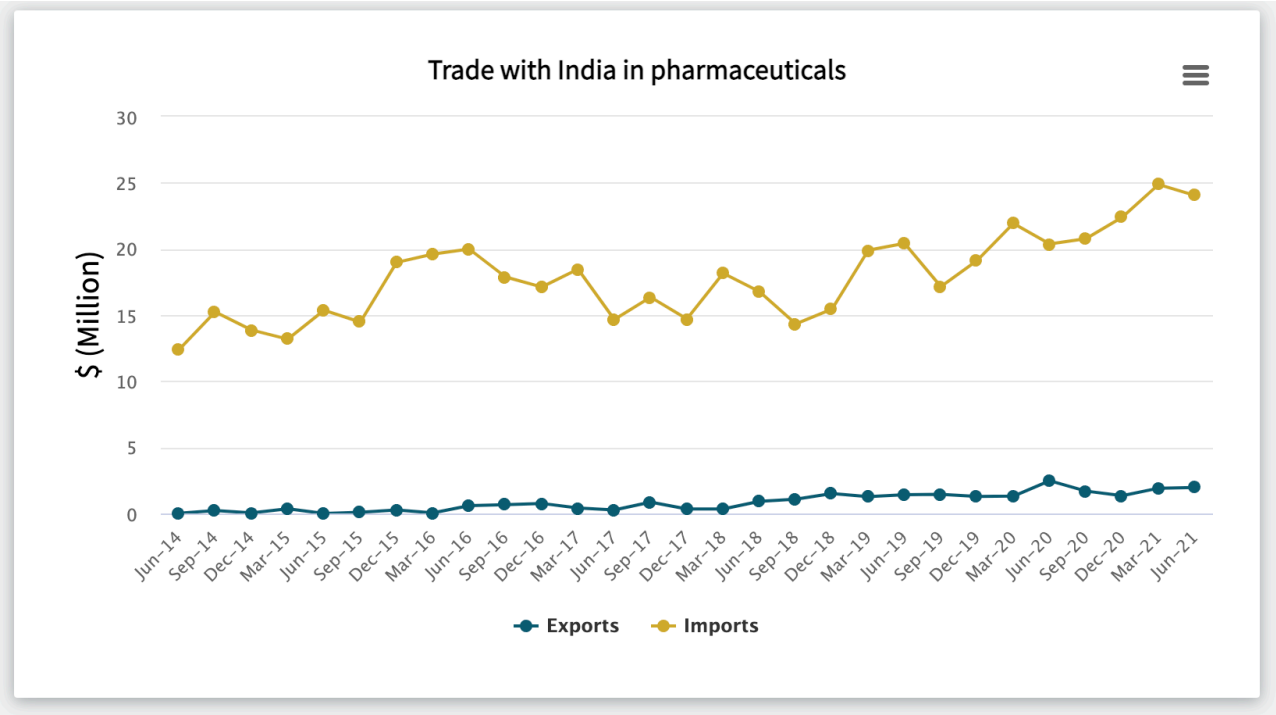


[Source: Stats NZ]

New Zealand's Trade with India – pharmaceuticals

In the June 2021 quarter New Zealand exported $1.97million of pharmaceuticals to India and imported $24.04 million, representing a trade balance of $-22.07 million and a total trade value of $26.01 million.

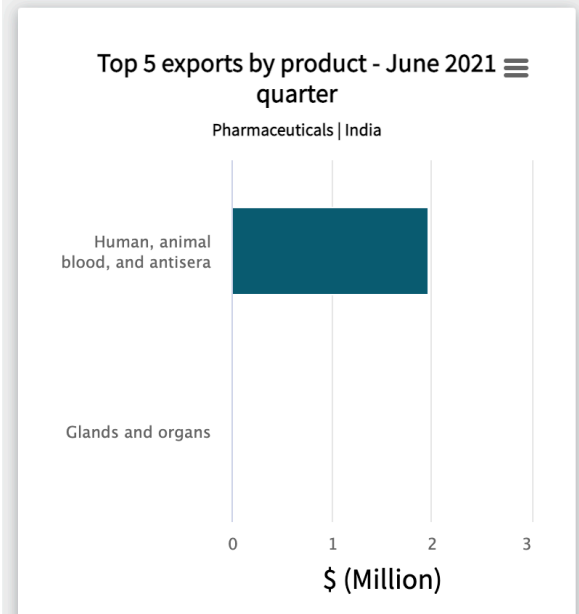
This represented 0.8% of all exports of pharmaceuticals in this time period and 2.8% of imports. For trade in pharmaceuticals, India ranked 11 of 83 for highest export value, 6 of 75 for highest import value, and 7 of 109 for highest total trade value. Additionally, this represented 1.5% of all goods exports to India and 12.2% of imports.



Top 5 products for export-import with India

[As on June 2021 quarter]

Exports



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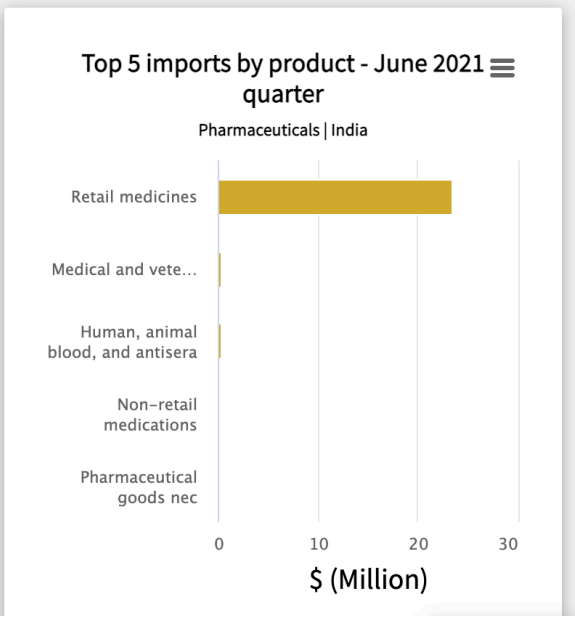


Chapter 2: Understanding the export journey

For any company to be able to export medicines into New Zealand, you need to have a local sponsor, i.e. a NZ based company that legally represents you.

Other alternative is to set-up your own company in New Zealand, however, that comes with substantial costs.

The NZ sponsor company will have local knowledge of the industry, the requirements, regulations, etc. It is the sponsor that will register your drug in New Zealand, apply to PHARMAC on your behalf or coordinate with agencies like Medsafe. The other roles they provide are marketing & distribution.

The process to get the work started may look like below:

Who is a Sponsor?

The Sponsor is the New Zealand entity - importer, exporter or local manufacturer - that has the legal responsibility for a medical device supplied in New Zealand. This responsibility includes ensuring that medical devices are notified to the Web Assisted Notification of Devices (WAND) database in accordance with the Regulations.

Legal Definition of a Sponsor

The legal definition of a sponsor is contained in Regulation 3 of the Medicines (Database of Medical Devices) Regulations 2003 and states;

sponsor, in relation to a medical device -

means -

- a person in New Zealand who exports, or arranges the exportation of, the device from New Zealand:
- a person in New Zealand who imports, or arranges the importation of, the device into New Zealand:
- a person in New Zealand who manufactures the device in New Zealand, or arranges for another person to manufacture the device in New Zealand, for supply (whether in New Zealand or elsewhere); but

does not include a person who -

- exports, imports, or manufactures a device; or
- arranges for the exportation, importation, or manufacture of a device - on behalf of another person who, at the time of the exportation, importation, manufacture, or making of the arrangements, is a resident of, or is carrying on business in, New Zealand

Key Criteria of a Sponsor

The interpretation of the above definition establishes the following criteria for a sponsor;

- A sponsor is based in New Zealand and must have a local presence (registered business or principal place of business in New Zealand)
- A sponsor imports, exports, or manufacturers medical devices in New Zealand
- A sponsor may arrange for a New Zealand based third party to manufacture a medical device on its behalf for supply anywhere
- A sponsor may arrange for an agent to import and distribute a medical device to New Zealand on their behalf. In these instances, the sponsor, and not the agent, has all the responsibilities of a sponsor which are listed below.

Note - A sponsor must have a presence in New Zealand. Organisations without a New Zealand presence cannot be sponsors.

A sponsor is NOT an individual or organisation that purchases products from a New Zealand based sponsor for resale within New Zealand.

Examples of Sponsors:

- A New Zealand entity (individual or organisation) importing devices into New Zealand for sale to the local market
- A New Zealand hospital directly importing a device from an overseas manufacturer
- A healthcare professional making a one off importation of a small number of devices, one of which he/she keeps, and reselling the balance
- A New Zealand entity parallel importing any medical device into New Zealand for sale to the local market
- A New Zealand entity importing a range of medical devices into New Zealand which it repackages as first aid kits for resale
- A New Zealand entity contracting a New Zealand third party to produce a first aid kit to the entity's specifications

Examples of entities that are NOT Sponsors:

- Overseas companies supplying product directly to New Zealand organisations (the importer is the legal sponsor.)
- An organisation or individual that purchases medical devices from a sponsor or that purchases medical devices that have been supplied by a sponsor.

Responsibilities of a Sponsor

A sponsor has the following responsibilities;

- To ensure that the device is safe for its intended purpose. (Refer Section 38 of the Medicines Act 1981.)
- To notify information about its medical devices to the WAND database within 30 working days of becoming the sponsor. (Refer Regulation 6 of the Medicines [Database of Medical Devices] Regulations 2003.)
- To ensure, should the information notified to the WAND database become inaccurate or incorrect, that it is corrected within 10 working days of the information ceasing to be accurate or correct. (Refer Regulation 8 of the Medicines [Database of Medical Devices] Regulations 2003.)
- To maintain distribution records of the devices supplied so that in the event of a recall or corrective action the sponsor can contact all affected users. (Refer to the Medsafe Uniform Recall Procedure.)
- To immediately advise Medsafe of any recall or corrective action affecting medical devices supplied by that sponsor in New Zealand. (Refer to the Medsafe Uniform Recall Procedure [PDF 469 KB, 49 pages].)
  [https://www.medsafe.govt.nz/safety/RecallCode.pdf]

- To ensure that the labelling of the medical devices complies with the Regulations. (Refer Regulation 12 of the Medicines Regulations 1984.)
- To ensure that any advertising for medical devices supplied by that sponsor complies with the requirements of the Medicines Act and Regulations. (Refer Part 4 of the Medicines Act 1981.)

Source: https://www.medsafe.govt.nz/regulatory/devicesnew/1Definition.asp#sponsor

For further reading, see reference:

[16] Medsafe: Regulation of Dietary Supplements

[17] Medsafe: Guidance for Natural Health Practitioners

Chapter 3: New Zealand Pharma Funding System

Overview:

New Zealand is the only country with a government agency like PHARMAC.

PHARMAC is the only agency in the world that both:

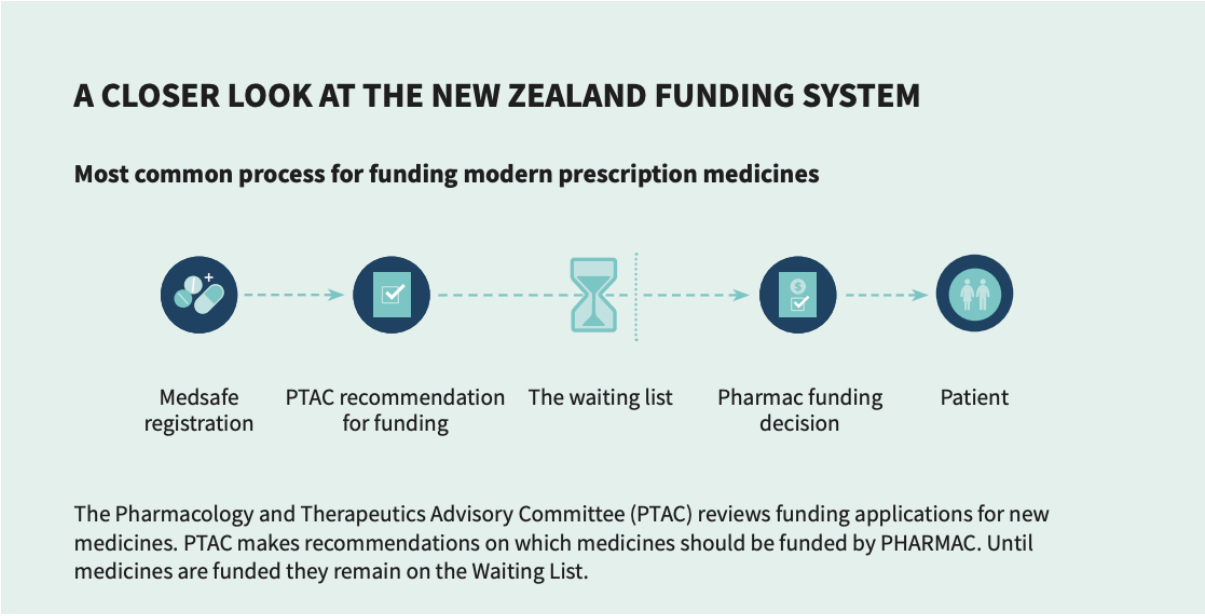
- decides what medicines to fund and
- manages a fixed budget for those medicines.

Industry Tip: They do not approve medicines, that's Medsafe's role. They make sure medicines work as they're supposed to.

PHARMAC does not make, buy or sell medicines. They are not profit driven. They are given a budget by the Government and they invest all of it on making sure New Zealanders can access medicines.

In 2019/20, PHARMAC managed $1.04 billion in spending on medicines. They invested all of it into medicines for New Zealanders.

PHARMAC currently funds nearly 1000 different medicines (in over 2000 different preparations). These are the medicines available in hospitals and from the local pharmacies.



[Source: PHARMAC]

How are medicines approved in New Zealand?

Companies who wish to sell a new medicine in New Zealand make an application to Medsafe (called a New Medicine Application or NMA). This application includes information that demonstrates the medicine meets New Zealand and internationally recognised standards for quality, safety and efficacy.

Medsafe reviews this information and makes a recommendation to the Minister of Health as to whether the medicine is approvable, or otherwise. If the medicine is approved, the New Zealand sponsor company then decides if the medicine will be supplied in this country.

Companies also submit notifications to Medsafe for planned material changes to an approved medicine (called a Changed Medicine Notification or CMN). Medsafe evaluates the change(s) to ensure that it does not affect the established quality, safety and efficacy of a registered medicine. Changed medicines cannot be marketed without the consent of the Director-General of Health (or delegate).

Medsafe is not responsible for funding or purchasing medicines in New Zealand. The government organisation responsible for determining which medicines will be publicly funded is PHARMAC.

What is the medicine evaluation process?

An application to approve a new medicine includes data supporting the medicine's quality, safety and efficacy.

An evaluation of the New Medicine Application is undertaken. If Medsafe considers the information to be inadequate it will request further information. Medsafe then reviews the response and makes a decision as to whether or not it can recommend to the Minister of Health that the medicine be granted consent to be marketed in New Zealand.

How long does this process take?

Medsafe aims to complete the various stages of a New Medicine Application evaluation within target time frames. There are also statutory timelines for the evaluation of Changed Medicine Notifications. The total time taken to reach a final decision can vary, and depends on the amount and complexity of the information provided, the amount of additional information requested and how long it takes the company to respond to Medsafe's requests for more information.

Tip: See more detailed information on Medsafe in chapter no 4.

Source: [4] Medsafe

How new medicines get funded by PHARMAC

Before PHARMAC can fund a medicine, they need an application to fund it. They receive most funding applications from pharmaceutical companies. PHARMAC also accepts applications from doctors and patients.

The Factors for consideration by PHARMAC are shown in the following diagram.

The circular diagram represents the four different dimensions/quadrants that PHARMAC will generally consider when making funding decisions (Need[1], Health Benefits, Costs and Savings, and Suitability), and the three levels of impact that they will usually take into account (to the person; to the person's family, [whanau] and wider society; and to the broader health system).

Ultimately, these factors help to ensure they meet PHARMAC's Statutory Objective: "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided".

The four Factors for Consideration are:

1. Need
2. Health Benefits
3. Costs and Savings
4. Suitability

Each factor has 3 different aspects:

- the individual
- the family, [whanau] and society
- the health system.

Putting the Factors to work

The factors help PHARMAC assess each funding application against its statutory objective. They help answer the question:

Does the proposal or decision help PHARMAC to secure for eligible people in need of pharmaceuticals the best health outcomes that are reasonably achievable from pharmaceuticals treatment and from within the amount of funding provided?

PHARMAC will mainly use the Factors for Consideration when making funding decisions, both decisions relating to treatments being listed on the Pharmaceutical Schedule, and also for decisions for individual patients through PHARMAC'S Named Patient Pharmaceutical Assessment Policy.

When relevant, they also endeavour to use these Factors when making other decisions that relate to their statutory functions set out in the New Zealand Public Health and Disability Act 2000. This could include making decisions to support the responsible use of medicines.

Not every factor may be relevant to every funding decision PHARMAC makes

Some factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required. Having the ability to exercise this judgement is critical to PHARMAC'S role as it enables them to respond appropriately to a broad range of situations.

Every funding decision must be considered in relation to the amount of funding available

PHARMAC considers every funding decision in relation to how funding the given treatment may impact on the Combined Pharmaceutical Budget, District Health Board (DHB) hospital budgets and the overall Vote Health budget as applicable, for both the current financial year and over future years.

Source: [3] PHARMAC

The Combined Pharmaceutical Budget is a fixed annual budget determined by the Minister of Health. Funding proposals for pharmaceuticals will be compared against one another using the Factors for Consideration, to determine which investments would result in the best health outcomes. Each funding proposal will then be ranked against all other funding proposals based on the results of this assessment. This is called the prioritisation process and the ranking helps PHARMAC decide which investments to progress within the fixed annual budget.

Tip: Detailed notes on how to make a funding application, available in chapter no. 5, on PHARMAC

Chapter 4: Medsafe

Introduction to Medsafe

What is Medsafe?

Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand.

Medsafe's mission is:
To enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit

Medsafe has around 60 staff operating out of two offices, with centralised administrative functions, product approval and standard setting based at the head office in Wellington. Investigation and Border Control functions are based in Auckland.

In carrying out its functions, Medsafe is accountable to the Ministry of Health, and through the Ministry to the Minister of Health. It is also accountable to the pharmaceutical industry for those activities which are funded by fees collected from the industry.

What products does Medsafe regulate?

Medsafe regulates products used for a therapeutic purpose. These include:

- medicines
- related products
- medical devices
- controlled drugs used as medicines

"Therapeutic purpose" is defined in Section 4 of the Medicines Act, and includes the treatment, diagnosis and prevention of disease or the modification of a physiological function. It also includes cleaning, soaking or lubricating contact lenses, effecting contraception or inducing anaesthesia.

"Medicine" is defined in Section 3 of the Medicines Act. A product is a medicine if it has a pharmacological effect and is used in humans primarily for a therapeutic purpose.

"Related product" is defined in Section 94 of the Medicines Act. It is a product that is primarily a food, dentifrice or cosmetic, but has a secondary therapeutic use. Examples of related products include throat lozenges and fluoride toothpastes.

"Medical device" is defined in Section 3A of the Medicines Act. Medical devices exert their therapeutic effect by physical rather than pharmacological means. The term covers products ranging from wound dressings to heart valves.

For further information about the products regulated by Medsafe and the types of controls used, you should:

- refer to the Medicines legislation; or
- refer to the New Zealand Regulatory Guidelines for Medicines Volume 1.

Pre-marketing approval must be obtained for new and changed medicines. **New medicines cannot be marketed in New Zealand without the consent of the Minister of Health.**

Medicines to which changes have been made cannot be marketed without the consent of the Director-General of Health. Data that satisfactorily establish the quality, safety and efficacy of the product, for the purposes for which it is to be used, must be submitted for evaluation before consent can be granted.

Post-marketing surveillance monitors the safety of medicines and medical devices in use. Products shown to be unsafe are removed from use, and prescribers are advised about new safety information for products. Post-marketing surveillance is achieved through activities such as:

- monitoring adverse reactions to medicines used in New Zealand and monitoring the international literature and other information sources;
- testing marketed medicines against product quality standards;
- handling complaints and investigations; and
- auditing and licensing medicine manufacturers.

Source: [4] About Medsafe

Medsafe's Evaluation and Approval Process

How are medicines approved in New Zealand?

Companies who wish to sell a new medicine in New Zealand make an application to Medsafe (called a New Medicine Application or NMA). This application includes information that demonstrates the medicine meets New Zealand and internationally recognised standards for quality, safety and efficacy.

Medsafe reviews this information and makes a recommendation to the Minister as to whether the medicine is approvable, or otherwise. If the medicine is approved, the New Zealand sponsor company then decides if the medicine will be supplied in New Zealand.

Companies also submit notifications to Medsafe for planned material changes to an approved medicine (called a Changed Medicine Notification or CMN). Medsafe evaluates the change(s) to ensure that it does not affect the established quality, safety and efficacy of a registered medicine. Changed medicines cannot be marketed without the consent of the Director-General of Health (or delegate).

Medsafe is not responsible for funding or purchasing medicines in New Zealand. The government organisation responsible for determining which medicines will be publicly funded is PHARMAC.

How can I know that a medicine has been approved for sale in New Zealand?

Medsafe lists all medicines that have been approved in New Zealand on its website, and any medicines where an application was submitted but approval was not granted.

This list includes information on where the medicine is made, the ingredients it contains, how it is packaged, what it is used for (indications) and who is legally responsible for the product (known as the Sponsor).

Tip: This information can be found on the Product/Application Search page: https://www.medsafe.govt.nz/regulatory/DbSearch.asp

[5] Medsafe Evaluation Process

What is the medicine evaluation process?

An application to approve a new medicine includes data supporting the medicine's quality, safety and efficacy.

An evaluation of the New Medicine Application is undertaken. If Medsafe considers the information to be inadequate it will request further information. Medsafe then reviews the response and makes a decision as to whether or not it can recommend to the Minister of Health that the medicine be granted consent to be marketed in New Zealand.

How long does this process take?

Medsafe aims to complete the various stages of a New Medicine Application evaluation within target time frames. There are also statutory timelines for the evaluation of Changed Medicine Notifications. The total time taken to reach a final decision can vary, and depends on the amount and complexity of the information provided, the amount of additional information requested and how long it takes the company to respond to Medsafe's requests for more information.

Information on Medsafe's evaluation timelines – See reference [6]

What data does Medsafe review in medicine applications?

- The acceptability of the proposed product trade name.
- Evidence of Good manufacturing practice (GMP) to demonstrate the medicines are consistently manufactured under acceptable quality standards.
- Chemical and biological data that supports the source, manufacture, characterisation, quantity, quality, storage and stability of the drug substance (active ingredient) and drug product (finished product).
- The quantity and quality of other non-active ingredients (excipients) present in the medicine.
- The formulation of the medicine (eg, tablet, suspension, capsule, injection).
- Agreed specifications (quality tests) that the medicine must meet before it is released to be sold or dispensed.
- Results of bioequivalence studies that evaluate the therapeutic equivalency of generic medicines and the corresponding brand name (innovator) products.
- Results of clinical studies in people that demonstrate new medicines are safe and effective for the treatment of a particular disease or condition.
- The quality of the medicine's packaging and the content of the medicine label.
- The information presented in the medicine data sheet and package insert (eg, consumer medicine information [CMI]).

What are the criteria used by Medsafe to establish the quality of a medicine?

Medsafe assesses medicine applications against internationally established criteria, such as guidelines published by the EMA (European authority), the FDA (USA), Health Canada, the TGA (Australia) and the International Conference on Harmonisation (ICH).

Medsafe does not test every medicine before it is approved. The assessment of a medicine application is based on information supplied to Medsafe. Manufacturers are regularly inspected by Medsafe or other international regulators to ensure they consistently produce high quality medicines.

All medicines, regardless of the country of manufacture, are assessed to the same requirements.

How is the efficacy of a medicine established before it can be approved?

Efficacy is a technical term used to describe how well the medicine works.

Clinical trials are undertaken by pharmaceutical companies to collect data on the efficacy of potential new medicines. These trials can be conducted using healthy volunteers or patients, depending on the type of medicine and its stage of development.

Clinical trials begin with small studies in a controlled population of volunteers or patients and, as data are gathered, expand to large scale studies in patients. These large scale studies investigate the new medicine in comparison with placebo or another established treatment.

Bioequivalence studies are designed to compare the rate and extent of absorption of the active ingredient(s) in a test generic medicine with that of a reference innovative medicine. If two medicines are demonstrated to be bioequivalent, it is considered that there would be no clinically significant difference in their bioavailability, and their efficacy and safety profiles are therefore considered to be the same. As a result, it would not normally be necessary to repeat clinical studies for generic medicines.

How is the safety of a medicine established before it is approved for use in New Zealand?

The pharmaceutical company responsible for that medicine provides Medsafe with safety information from clinical studies performed using that medicine. If the medicine has also been supplied elsewhere the company will also provide data from use in that country. The extent of the clinical studies varies depending on the type of medicine application.

Medsafe evaluates the results from these clinical studies to determine if the safety profile is acceptable.

Medsafe reviews the risks and benefits for each specific medicine to ensure that the safety profile is acceptable (ie, the benefits of the medicine outweigh the risks).

The following factors are taken into consideration.

Benefits

- Has efficacy been demonstrated in the target population (ie, those who will use the medicine)?
- Is the medicine significantly better than a placebo?
- How does the medicine compare to any alternative treatments?
- How many people have the condition that this medicine will treat or prevent?
- What is the natural history of the disease?
- Is it self-limiting, chronic or fatal?

Risks

- What proportion of people taking the medicine experience an adverse reaction?
- How many of these adverse reactions are considered to be serious?
- How many people stopped treatment because of an adverse reaction?
- Are the adverse reactions reversible, treatable or avoidable (eg, interactions with other medicines)?

Source: [5] Medsafe Evaluation Process

Is my product a medicine?

The first thing you need to do is work out if your product is a medicine. You need to answer the below 2 questions:

- Does your product have a therapeutic purpose or do you want to state a therapeutic claim?
- Does your product contain a scheduled ingredient?

Does your product have a therapeutic purpose or do you want to state a therapeutic claim?

If your product has a therapeutic purpose or makes a therapeutic claim then it is a medicine, related product or medical device.

A therapeutic purpose is defined in section 4 of the Medicines Act 1981. It includes the treatment, diagnosis and prevention of disease, or the modification of a physiological function. It also includes effecting contraception or inducing anaesthesia.

It can be difficult to determine whether a claim implies a therapeutic purpose. For advice on this, the Association of New Zealand Advertisers website has guidelines on therapeutic claims and provides examples of claims that do not imply a therapeutic purpose.

[See reference 9 for guidelines]

For further advice, there are a number of regulatory consultants who can help.

Tip: Please see appendix for list of regulatory consultants

Does your product contain a scheduled ingredient?

If your product contains a scheduled ingredient then it is a medicine.

Medicines are generally scheduled (ie, classified) according to their active ingredients. The First Schedule to the Medicines Regulations 1984 is a list of ingredients classified as prescription, restricted or pharmacy-only medicines.

You can check your ingredients using Medsafe's searchable database. Search by both the name you know the ingredient by and any synonyms. If you do this and get a 'no substances were found' result, it is unlikely that the ingredient is scheduled under the Medicines Regulations 1984. [Link: https://www.medsafe.govt.nz/profs/class/classintro.asp]

Note - if you find the ingredient is not scheduled, your product may still be a medicine if the ingredient has a therapeutic purpose. For example, certain strengths of paracetamol are unscheduled but this ingredient has a therapeutic purpose and so the product is a medicine.

If your product is not a medicine, it may be a:

- **Related product:** A related product is a product that is primarily a food, dentifrice or cosmetic, but has a secondary therapeutic use. The consent of the Minister of Health is required before a new related product can be sold in New Zealand.
- **Medical device**
- **Dietary supplement**
- **Food:** A food falls under the jurisdiction of the Food Act 1981 and is regulated by the Ministry for Primary Industries. There are numerous Food Standards that apply to foods (eg, the New Zealand Food [Supplemented Food] Standard 2010). The Ministry for Primary Industries publishes a New Zealand Supplemented Food Standard - User Guide which will help you. For further information on food and supplemented food regulations, contact the Ministry for Primary Industries [https://www.mpi.govt.nz/food-business/]
- **Cosmetic:** A cosmetic is a product used to cleanse, protect or beautify the hair or skin. Cosmetics must not have a therapeutic purpose or contain a scheduled ingredient. A product marketed as a cosmetic must comply with the Cosmetic Products Group Standard 2006 , which is published by the Environmental Protection Authority. Further information on Cosmetics can be found on the Environmental Protection Authority website. [Link: https://www.epa.govt.nz/industry-areas/hazardous-substances/guidance-for-importers-and-manufacturers/cosmetics/]. Regulations 24 and 26-36 of the Medicines Regulations 1984 also have requirements that apply to cosmetics.

  There is no approval or registration process in New Zealand for cosmetics that meet these requirements. It remains the responsibility of the sponsor (ie, you) to ensure the cosmetic is made to an acceptable quality and is safe to use.

- **Psychoactive product:** A psychoactive substance is anything that is capable of inducing a psychoactive effect in an individual who uses the psychoactive substance. Controlled drugs, medicines, herbal remedies, dietary supplements, food, alcohol and tobacco are excluded from the definition of a psychoactive substance.

  Psychoactive products must meet the requirements of the Psychoactive Substances Act 2013 and are regulated by the Office of the Psychoactive Substances Regulatory Authority.

  Psychoactive products require approval from the Psychoactive Substances Regulatory Authority before they can be marketed in New Zealand. Only products that are approved psychoactive products should make claims that imply a psychoactive or mood altering effect.

  For further information on psychoactive products, contact the Psychoactive Substances Regulatory Authority [Link: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/psychoactive-substances-regulation].

Tip: [7] See detailed information on categorisation of products:

https://www.medsafe.govt.nz/regulatory/categorisation-of-products.asp

Source: [8] Medsafe: Regulatory Guidance

What do I need to do to sell my medicine in New Zealand?

Medicines and related products need consent from the Minister of Health before being sold in New Zealand. As part of this process, an application needs to be submitted to Medsafe.

In order to submit an application you will need to think about all of the following factors:

Type of application

If your product is a medicine, you will need to submit a New Medicine Application together with supporting data.

If your product is a related product, you will need to submit a New Related Product Application together with supporting data.

Forms

You will need to submit a New Medicine or Related Product Application Form.

Medsafe has developed guidance on how to complete this form.

View documents 14 to 22 in the list of Forms for further guidance.

[See reference 10: Forms & Templates]

Supporting data

Information required in your application includes data demonstrating the safety, efficacy and quality of the ingredients and of your final product. Efficacy is a technical term used to describe how well a medicine works.

You will need to show the safety and efficacy of your product in the treatment of humans. Evidence will need to be provided from clinical trials or by providing robust, scientific peer reviewed literature. Medsafe cannot accept evidence of traditional use or testimonials to support your efficacy claims.

Data to show the quality of your product during its shelf-life will also need to be submitted.

Supporting data can range in size from a few hundred pages to a few hundred boxes, depending on the type of your application.

View Part 2 of the Guideline on the Regulation of Therapeutic Products in New Zealand for further guidance on supporting data. [See reference 10]

Good manufacturing practice (GMP)

Your product will need to be made in a facility that complies with good manufacturing practice.

Good manufacturing practice describes the systems, manufacturers of medicines are required to have in place to ensure products are consistently safe, effective and of acceptable quality. The requirements are described in a code of practice called the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods. [See reference 12]

If your product is not made in New Zealand, you will also need to think about the requirements for commercial importation. The New Zealand Customs Service is able to advise you on this. [Link: https://www.customs.govt.nz/business/]

Sponsor responsibilities

The sponsor is the person or company legally responsible for placing the product on the market in New Zealand.

As sponsor you must have a physical address in New Zealand.

For further guidance on sponsor responsibilities, view:

- regulation 50 of the Medicines Regulations 1984
- sections 17, 21, 29, 41, 42 and 57 of the Medicines Act 1981

[See Reference 13]

Source: [8] Medsafe: Regulatory Guidance

Medical Devices

The Web Assisted Notification of Devices (WAND) Database

For medical devices to be legally supplied in New Zealand they must be notified to the WAND database. Notification of medical device information to the WAND database is free and there are no on-going fees. Devices must be notified to the WAND database within 30 calendar days of a person or organisation becoming the sponsor of the device.

Medical Device Manufacturer

Individuals and organisations manufacturing medical devices in New Zealand should ensure the devices are correctly notified to the WAND database. Manufacturing includes assembling of kits of medical devices (ie, first aid kits) as well as device fabricators.

Explanation of the WAND Database

The WAND database was established by the Medicines (Database of Medical Devices) Regulations 2003 to collect information about medical devices supplied in New Zealand. It is a mandatory requirement for importers, exporters and local manufacturers to notify their medical devices to the database. WAND is not an approval system for medical devices.

WAND is NOT an approval system

There is no approval system for medical devices under the Medicines Act 1981. There is no mandatory requirement for medical devices to be approved by any medical device regulator prior to being supplied in New Zealand. Notification to the WAND database does not mean or imply that a medical device has been assessed by Medsafe in terms of quality, safety, efficacy, or performance.

It is, though, a mandatory requirement for importers, exporters and New Zealand manufacturers to advise the Director-General of Health, via the WAND database, of the devices that are supplied here.

Purpose of the WAND database

The WAND database holds information about all medical devices supplied in New Zealand and is used by Medsafe to respond to information about medical device safety issues. If there is a safety issue with a device the WAND database is used to identify all sponsors of that device.

Source: [14] Medsafe: Medical Devices

How Medsafe uses WAND information

Medsafe has a role to monitor post-market activity in relation to medical devices and to take action when required to ensure devices continue to meet legislative requirements with respect to safety. Medsafe used the information in WAND to identify sponsors of products when necessary in order to make contact when post market issues have been raised through international or local reports.

Charges associated with the WAND database

There are no charges associated with the database. All information is submitted free of charge to the WAND database.

Source: [15] Medsafe: Definitions

Chapter 5: PHARMAC

Overview

PHARMAC is a government agency and the only agency in the world that both:

- **decides what medicines to fund and**
- **manages a fixed budget for those medicines.**

PHARMAC does not approve medicines, that's Medsafe's role. Medsafe ensures that the medicines work as they are supposed to. The Public Health and Disability Act sets out PHARMAC's role.

PHARMAC does not make, buy or sell medicines. They don't make a profit. They are given a budget by the Government and they invest all of it on making sure New Zealanders can access medicines.

It's not all about funding new and more medicines

Many people focus on improving access to new medicines. But the focus of PHARMAC is to get the funded medicines to people affected by inequity including:

- Māori
- Pacific Peoples
- People who live rurally

It's not enough to define access solely based on whether a medicine can be prescribed to someone. It also matters that they can get it and use it. The medicines PHARMAC funds can help people live better and healthier lives.

PHARMAC wants to improve access for all New Zealanders to the medicines they already fund. This will have the greatest benefit to New Zealand.

Managing New Zealand's medicine budget

The Public Health and Disability Act says PHARMAC must decide which medicines to fund for the best health outcomes for New Zealanders, while staying within their budget.

In 2019/20, PHARMAC managed $1.04 billion in spending on medicines. They invested all of it into medicines for New Zealanders.

They currently fund nearly 1000 different medicines (in over 2000 different preparations). These are the medicines available in hospitals and from the local pharmacies. Every year,

the budget needs to pay for these funded medicines. If there is money left after that, PHARMAC can consider funding new medicines.

Finding the money for new medicines

Since 2014, PHARMAC's budget has increased a little every year. These increases covered the costs of population growth and normal inflation. They sometimes get a big increase to meet a specific goal, such as the extra costs caused by COVID-19.

To free up enough budget to fund new medicines, PHARMAC reduces the cost of the medicines they already fund. Once a medicine is funded, generally, it stays funded.

PHARMAC has been very successful at negotiating the costs of medicines. These savings have allowed them to fund more new medicines every year.

How new medicines get funded ?

Before PHARMAC can fund a medicine, they need an application to fund it. They receive most funding applications from pharmaceutical companies. They also accept applications from doctors and patients.

Ask the experts

Usually, the first step is to get advice fr4om their own clinical experts. 140 clinical experts make up their clinical committees. They assess all the scientific evidence.

The experts panel includes doctors, specialists, nurses and others who are treating people. These experts see how medicines and other treatments can improve people's lives.

PHARMAC has an overarching committee called Pharmacology and Therapeutics Advisory Committee (PTAC). There are also subcommittees which advise PTAC.

What kind of advice do they get?

PTAC will recommend whether PHARMAC should fund an application or not.

They may recommend that they decline an application because it adds no value or is harmful.

PTAC might say that a medicine works well, but that PHARMAC already funds medicines that are just as good. So they may recommend to fund those medicines if they don't cost any extra (are cost neutral) or PHARMAC can save money with them.

If they recommend funding a medicine, they will give it a low, medium or high priority.

What happens when the experts suggest to decline an application?

For transparency, PHARMAC consults before they formally decline an application. Anyone can comment on the consultation.

They have officially declined 77 applications in the past. They had proposed 92 applications for decline, but feedback suggested that they keep some applications open.

PHARMAC needs to know all the costs and benefits

Following a recommendation from PTAC, they investigate the cost and benefits of each medicine. They don't just look at how much, in dollar terms, a medicine costs. PHARMAC looks at a number of factors including:

- how improved people's lives might be and for how long with the medicine
- how much shorter or less healthy people's lives would be without the medicine
- how a patient's whānau will be affected by a funding decision. For example, if whānau are caregivers, a treatment may reduce the level of care needed.

Every funding application is given the same methodical analysis.

Deciding which new medicines to fund

PHARMAC compares each application against all the other applications. Then they decide what medicines are in their priorities to fund.

The priority of the medicines on their 'options for investment list' is a closely guarded secret. They need this secrecy to strengthen their bargaining position.

As at November 2020, there were about 75 medicines on the priority list. These are medicines PTAC have recommended for funding with a low to high priority. About 12 were considered high priority.

When will the medicine be funded?

Before PHARMAC can fund a medicine, they need:

- a clear health benefit for New Zealanders
- a deal with a medicine supplier
- enough money in the budget to fund it this year, and future years
- to consult on the proposal with everyone who may be interested.

Once these align, PHARMAC works quickly to fund a medicine for New Zealanders.

Further Reading: [19] Mythbusting PHARMAC

Source: [18] How PHARMAC works

How the health priorities affect PHARMAC's work

PHARMAC uses the Government's health priorities when considering funding a medicine or medical device.

Overarching priorities

Priority 1: Child wellbeing

PHARMAC's decisions will help improve child wellbeing and support children to have a healthy start in life.

Priority 2: Mental wellbeing

PHARMAC's decisions will help improve mental wellbeing. For PHARMAC, this includes treatment for alcohol and drug addiction.

Priority 3: Prevention

PHARMAC's decisions will improve wellbeing by preventing health conditions.

In his 2020/21 Letter of Expectations to PHARMAC, the Minister of Health asked PHARMAC to "consider how the prioritisation of medications to support improving wellbeing through prevention should be addressed".

This includes issues such as:

- smoking cessation
- immunising against infectious diseases
- antimicrobial stewardship
- sexual health.

Priority 4: Health equity

PHARMAC's decisions will support better population outcomes, supported by a strong and equitable public health and disability system.

They are focused on achieving equity in health outcomes and enhancing equitable access to medicines. This includes a specific focus on achieving pae ora (healthy futures) for Māori as Te Tiriti partners.

PHARMAC's equity priorities

- Priority populations: Māori, Pacific people, low socio-economic status, refugees, rural populations.
- Priority health conditions: cardiovascular disease, diabetes, asthma, COPD, gout.

- Hauora Arotahi: PHARMAC's Hauora Arotahi (Māori health areas of focus) are -
    - mental health
    - diabetes
    - heart health
    - respiratory health
    - cancer (lung and breast)

Priority 5: Primary health care

PHARMAC's decisions will support better population health and outcomes supported by primary care. They are focused on strengthening primary care through making medicines available and accessible in primary care settings.

Specific health conditions

These conditions are government priorities. In addition to these priorities, PHARMAC takes into account a range of factors when making decisions.

Rare diseases

This covers conditions that meet PHARMAC’s definition of a rare disease (1:50,000 population).

Cancer

PHARMAC considers all cancer conditions. However, note that some specific cancers (lung and breast) have a particular focus for PHARMAC under the Hauora Arotahi Māori health areas of focus.

Long-term conditions

It considers diseases that have long-term conditions include:

- diabetes
- cardiovascular disease
- chronic respiratory disease
- neurological diseases (such as dementia).
- Infectious diseases

This covers both treatments for and immunisation to prevent infectious diseases.

PHARMAC also continue to promote the responsible use of antimicrobials (including antibiotics) – antimicrobial stewardship.

Further Reading: Please see earlier section on factors in consideration for funding.

Source: [20] How the health priorities affect PHARMAC's work

How PHARMAC gets clinical advice into their decision-making

Medical advice

PHARMAC requires good advice from clinicians to make decisions on medicines funding.

This advice is received in a number of ways, including through expert committees. PHARMAC also keeps up-to-date with the latest clinical information through ongoing professional development, monitoring of trial results and medical journal articles.

PTAC

The main clinical advice comes from an expert committee of medical practitioners, the Pharmacology and Therapeutics Advisory Committee. PTAC has been part of the health system since the 1950s and, in 1993, began providing advice to PHARMAC.

PTAC's role & relationship to PHARMAC

PTAC considers clinical evidence around funding applications, and takes into account PHARMAC's Factors for Consideration before making recommendations to PHARMAC on medicines funding. The Factors for Consideration are part of PHARMAC's Operating Policies and Procedures.

Read more about the Factors for Consideration: Reference [3]

PTAC members are not employed by PHARMAC (although they are reimbursed for the time they give to serving on the committee).

The committee has 10 members who have expertise in examining clinical studies and broad experience and knowledge of medicines and the conditions they treat. PTAC meets four times a year and the Chair of PTAC attends PHARMAC Board meetings as an observer and to share PTAC's views directly with the Board.

PTAC makes recommendations to PHARMAC to help us make decisions. PTAC operates under defined Terms of Reference which are available on PHARMAC's website. The Terms of Reference were reviewed in 2021.

How are PTAC members appointed?

Members are appointed by the Director-General of the Ministry of Health. Membership terms are usually three years and may be renewed. The process for appointing members is explained in an Appointment Protocol, also available on PHARMAC's website.

What does PTAC take into account when providing advice?

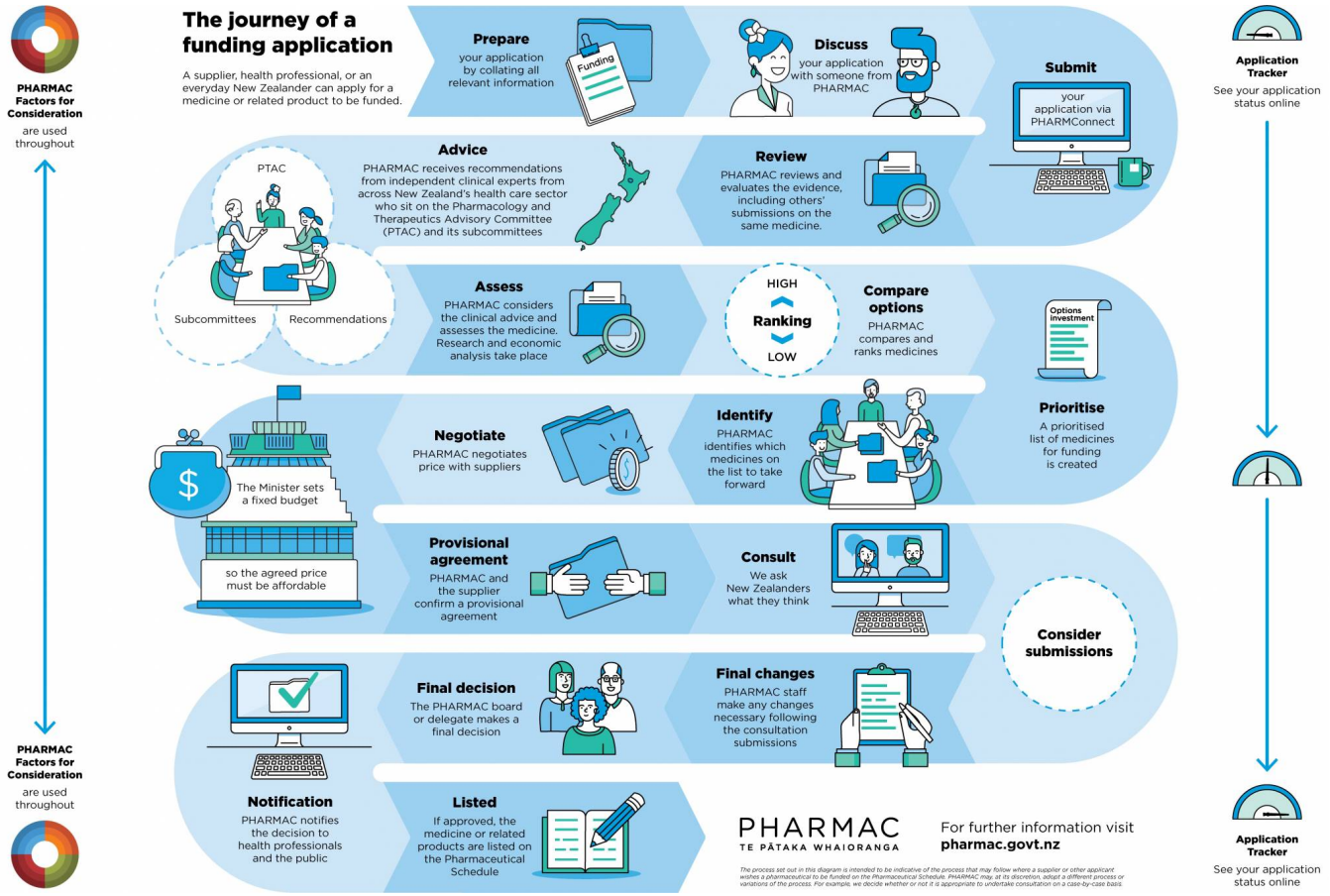
PTAC applies the same decision-making framework as the PHARMAC Board when making recommendations. Some stakeholders have suggested that PTAC should focus exclusively on clinical effectiveness, since that is its major expertise. As clinicians, however, PTAC members are also concerned with, and can usefully comment on, other factors including cost and opportunity cost, health inequalities and health need.

Source: [21] How PHARMAC gets clinical advice into their decision-making [further reading]

From application to funded medicine: PHARMAC's process

PHARMAC has a process for all funding applications to ensure that every application is treated fairly. Their job is to prioritise which new medicines will deliver the best possible health outcomes for New Zealanders.

See the application flowchart:



Source: PHARMAC | Download in PDF: https://pharmac.govt.nz/assets/PHARMAC-Funding-on-a-page-diagram.pdf

A supplier, health professional, or an everyday New Zealander can apply for a medicine or related product to be funded. The following steps are required:

1. Prepare your application by collating all relevant information.
2. Discuss your application with someone from PHARMAC.
3. Submit your application via PharmConnect.
4. Review: PHARMAC reviews and evaluates the evidence, including others' submissions on the same medicine.

5. Advice: PHARMAC receives recommendations from independent clinical experts from across New Zealand's healthcare sector who sit on the Pharmacology and Therapeutic Advisory Committee (PTAC) and its subcommittees.
6. Assess: PHARMAC considers the clinical advice and assesses the medicine. Reasearch and economic analysis take place.
7. Compare options: PHARMAC compares and ranks medicines, high to low.
8. Prioritise: A prioritised list of medicines for funding is created.
9. Identify: PHARMAC identifies which medicines on the list to take forward.
10. Negotiate: PHARMAC negotiates price with suppliers. The Minister sets a fixed budget, so the agreed price must be affordable.
11. Provisional agreement: PHARMAC and the supplier confirm a provisional agreement.
12. Consult: PHARMAC asks New Zealanders what they think.
13. Consider submissions.
14. Final changes: PHARMAC staff make any changes necessary following the consultation submissions.
15. Final decision: The PHARMAC board or delegate makes a final decision.
16. Notification: PHARMAC notifies the decision to health professionals and the public.
17. Listed: If approved, the medicine or medical device is listed on the Pharmaceutical Schedule.

PHARMAC 's Factors for Consideration are used throughout this process.

You can see the status of your application in their Application Tracker.

Disclaimer by PHARMAC: The process set out in this diagram is intended to be indicative of the process that may follow where a supplier or other applicant wishes a pharmaceutical to be funding on the Pharmaceutical Schedule. PHARMAC may, at its discretion, adopt a different process or variations of the process. For example, we decide whether or not it is appropriate to undertake consultation on a case-by-case basis.

Note that implementation of a decision includes both positive and negative funding decisions. These may include notification of a Schedule listing or listing that an application has been declined.

Source: [22] From application to funded medicine: PHARMAC's process

Procurement & tendering process

When a medicine is no longer under patent, other suppliers are able to sell a generic version of that medicine. This allows for competition and can lead to significant price reductions.

This competition can take place in PHARMAC's annual Invitation to Tender (ITT). The annual Tender is key in helping PHARMAC keep up with increasing demand for medicines they fund, and for new and innovative medicines.

This process creates savings of $30-50 million every year for PHARMAC.

This money is reinvested to get more medicines for more people through new investments or making existing medicines available to even more people.

PHARMAC's annual tender has now developed into a process often involving over 500 line-items. It is a quick and efficient way to secure supply and drive value from pharmaceutical markets. Where savings are achieved through the tender, PHARMAC is able to:

- Manage expenditure in growing medicine markets; and
- Free up funding so that they can invest in new medicines

This video below explains why the Tender is an important part of PHARMAC's toolkit to help New Zealanders live well, get well and stay well.

See video on Youtube: https://youtu.be/nJcsgkmRRww

Source: [23] Procurement & tendering process

How does the annual tender work?

The tender follows the same cycle every year:

Drafting (May – July): PHARMAC considers the types of products that could be included in the Tender and compiles a list of these products for consultation.

Consultation on draft Tender (July – August): Once the draft Tender has been put together, PHARMAC seeks feedback from suppliers, clinicians, health care professionals, the wider health sector and patients. They'll provide feedback on whether it's appropriate to include an item in the tender, and what things PHARMAC should consider during evaluation.

Consideration of consultation feedback (August – October): Following consultation, PHARMAC will consider the feedback, and seek additional information from the PTAC Tender Medical Evaluation Sub Committee if required before finalising the Tender.

Finalising the Tender (October): PHARMAC finalises the products to be included in the Tender for that year, after considering any consultation feedback.

Invitation to Tender (early-November): PHARMAC issues the tender and invites suppliers to provide bids on the products included in the Tender and alternative commercial proposals (ACPs).

Bids due from suppliers (mid-December): Suppliers have approximately 6 to 7 weeks to provide a bid for a product in the Tender. Suppliers can do this on their secure electronic portal. [Link: https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/new-electronic-portal-for-bidding-on-pharmacs-annual-tender/]

Samples requested (January – February): As a part of the evaluation process, PHARMAC may request samples of products from suppliers. PHARMAC will seek advice from clinical experts, including the Tender Medical Evaluation Subcommittee (TMESC), to see if the product is clinically and practically suitable to be included. Some of the things they look at include:

- the packaging - is it easy to store, is it easy to get into
- the labelling - is it easy to read and understand and follows the PHARMAC labelling guidelines
- the tablets – is it easy to break along the score lines, are they easy to swallow
- the taste – will the taste of the medicine stop some people taking the medicine

Awarding bids (February onwards): PHARMAC will evaluate the bids and make recommendations to the Board or delegate for listing The results of these are published in a monthly Tender notification on the PHARMAC website. The winning bidder gets to be the sole supplier of the medicine for a fixed term (usually three years)

Expert clinical and technical advice

Clinical and technical advice is an important part of the review of the tenders that are received. PHARMAC gets this advice from the Tender Medical Evaluation Subcommittee (TMESC) – made up of a range of health professionals including community and hospital pharmacists, GP, nurse, hospital doctors.

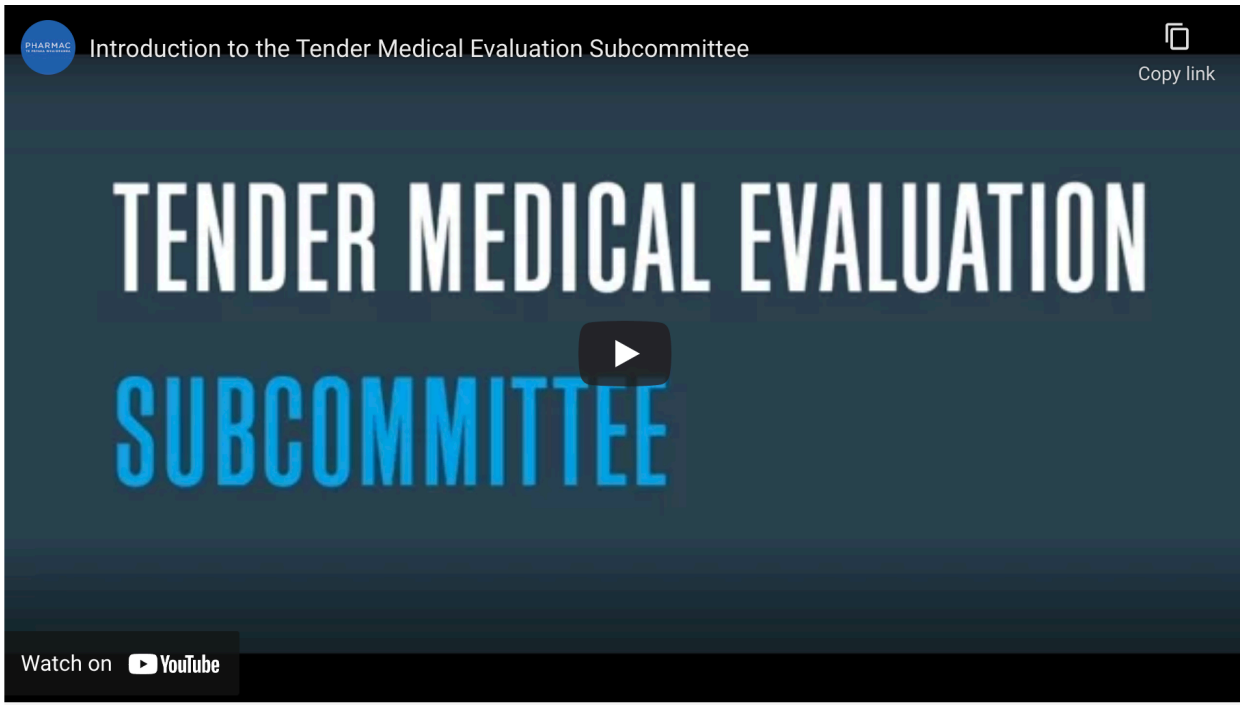
[See more about specialist advisory committees: reference 25]

Their role is to evaluate:

- **the packaging** - is it easy to store, is it easy to get into
- **the labelling** - is it easy to read and understand and follows the PHARMAC labelling guidelines
- **the tablets** – is it easy to break along the score lines, are they easy to swallow
- **the taste** – will the taste of the medicine stop some people taking the medicine
- **risk** – is it okay having a medicine on sole supply
- **other** clinical and technical details of the bids

Watch the video below for more information on the TMESC and what they do:

Watch on YouTube: https://youtu.be/Ts4Nx58Yj7Y



Receiving a funding application

Funding applications can be for a new medicine or wider access to a medicine that is already funded.

IMP: How to make an application: Reference [24] Make an application

SEE: New Zealand Government Electronic Tenders Service (GETS)portal:

https://www.gets.govt.nz/ExternalIndex.htm

Source: [23] Procurement & tendering process

Myths & FAQs on tendering process

Some common myths and facts about the tendering process, as presented by the CEO of PHARMAC, Sarah Fitt:

Myth	Fact
Take the lowest bid price.	Price is important, BUT there are many other factors taken into account.
Tender decisions are made without seeking clinical advice.	All tender decisions require advice from PHARMAC's clinical committee which includes practicing doctors, nurses and pharmacists.
Sole Supply agreements will increase the risk of an out of stock situation.	Incentive to commit to supplying New Zealand ahead of other markets. Safeguards in place to mitigate out of stocks or potential out of stocks.
Savings achieved through tender will be hard to maintain.	No signs of decreasing.
Competition in the market will be reduced by tendering and awarding sole supply.	Increased number of suppliers.

Hospital Medical Devices

What is a medical device?

- Products and equipment used on, in or by a person for diagnostic or therapeutic purpose
- Simple dressings to complex systems of clinical equipment
- Supportive devices with therapeutic / safety considerations (beds and mattresses, disability support devices)
- Includes devices provided by the hospital to community patients

Building the list – national contracting

- Allows hospital to buy the same products they're currently using on common
- terms for price and supply
- Requires hospitals to use national contract price & terms if purchasing contracted items
- Over $400 million spend pa currently under agreement (of an estimated $675 million)
- Over 138,000 contracted line items from over 100 suppliers

Fairer access to hospital medical devices

- PHARMAC will decide which devices are publicly funded to get the best possible health outcomes
- Hospitals will decide what devices they will use to deliver local services, chosen from a national list managed by PHARMAC
- PHARMAC will decide what gets added or removed, and will manage a process for exceptional circumstances

Tip: More guidance on medical devices is given earlier in this paper.

Source: presentation by CEO of PHARMAC, Sarah Fitt to INZBC on 17 Sep 2021.

Vaccines: PHARMAC's role

PHARMAC lists all publicly funded vaccines in the Pharmaceutical Schedule.

Unlike other medicines, PHARMAC purchases and maintains a stock of all funded vaccines. The influenza (flu) vaccine and covid-19 vaccine are managed differently.

How PHARMAC decides what vaccines to list in the Schedule

Vaccines are added to the Pharmaceutical Schedule the same way as any other medicine. Someone, usually a vaccine supplier, applies to PHARMAC to fund a vaccine.

PHARMAC then convenes the Immunisation Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC). The Subcommittee gives us clinical advice on vaccine funding applications and other matters.

Browse the National Immunisation Schedule (Section I of the Pharmaceutical Schedule) which lists all funded vaccines: reference [27]

The Ministry of Health maintains a separate list, also called the National Immunisation Schedule. It lists the vaccines that are offered free to babies, children, adolescents and adults.

Read the National Immunisation Schedule – Ministry of Health website: reference [28]

Covid-19 vaccine

PHARMAC was part of the all-of-government team that secured agreements for four different Covid-19 vaccines for New Zealanders.

Read more on this topic: https://pharmac.govt.nz/news-and-resources/covid19/covid-19-vaccines/

Who can get vaccinated

PHARMAC manages eligibility for funded vaccines. They target the funding for vaccines to ensure those who will benefit most can get vaccinated.

Deciding how much to buy

Some vaccines take a long time to make (up to 18 months). This can make knowing how much vaccine to buy difficult as PHARMAC needs to forecast so far in advance of when it's needed.

For example, they did the forecasting for 2020's pneumococcal vaccine in mid-2019, before the covid-19 virus was even heard of. PHARMAC considers a range of factors when forecasting vaccine usage, including:

- population changes
- recent demand for the vaccine
- any special programmes the Ministry of Health or DHBs may have planned
- other events that might change the demand for vaccines, such as outbreaks overseas.

Vaccine distribution

PHARMAC contracts a pharmaceutical wholesaler to run the National Vaccine Store. When a vaccine supplier delivers the vaccine that they ordered, it gets delivered to the National Vaccine Store.

Depending on the vaccine, they usually hold between 4 and 6 months' stock at any time. For many vaccines, deliveries are received every month.

Distributing to the regions

PHARMAC also contracts a pharmaceutical wholesaler to run the Regional Vaccine Stores. These stores are located around New Zealand. The health professionals who administer publicly funded vaccines get the vaccine from their nearest Regional Vaccine Store.

Making sure there's enough vaccine

PHARMAC aims to to have a supply of vaccine available to meet the forecast demand. There may be times when unexpected changes in supply or demand affect the amount of stock that is available. PHARMAC maintains a safety buffer in case of unexpected events and they work closely with suppliers to manage any supply issues.

For all other medicines (and the flu vaccine), it's the responsibility of the suppliers to ensure there's enough stock in New Zealand when needed.

Source: [26] Vaccines - PHARMAC's role

Chapter 6: Medicines New Zealand

Overview & Objective:

Medicines New Zealand advocates to improve access to modern medicines for New Zealand patients. Medicines New Zealand is an industry association whose members are engaged in the research, development, manufacture and marketing of modern prescription medicines. Medicines that are recognised as life changing, breakthrough or leading therapies.

They work with key health-based decision makers and a wide range of stakeholders to discuss industry perspectives. Medicines NZ informs and educates using only fact-based arguments with a goal of improving access to modern medicines for New Zealand patients.

Their stated vision:

"Collaborative: They work with other critical stakeholders in the health sector to deliver the best modern cost-effective medicines for all New Zealanders now and into the future.

Accountable: They are responsive and responsible to their members and New Zealanders.

Results: They save, improve and extend lives.

Ethical: They take a responsible approach and use evidence-based arguments."

In 2021, Medicines New Zealand joined the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) as a full member. [https://www.ifpma.org/]

Learn more about Medicines NZ: www.medicinesnz.co.nz

Public Perceptions of Medicines Funding in New Zealand

Key Findings of two National Online Surveys - June 2020

By Medicines NZ

Common Themes from the Surveys

- Approximately half of New Zealanders surveyed are concerned about prescription medicines access in New Zealand
- Approximately half of New Zealanders surveyed appear to think that Australia provides better publicly funded access to medicines than New Zealand
- New Zealanders think that more money, or a greater proportion of the public health budget, is necessary to provide New Zealanders' with appropriate access to medicines

Source: https://www.medicinesnz.co.nz/

A Decade of Modern Medicines: An International Comparison 2011 – 2020

In a recent report commissioned by Medicines NZ, an international comparison was made with New Zealand, on the funding of modern medicines. [Nov 2021]

Executive Summary:

[quoted from the report]

In this report we compare publicly funded access to modern medicines in New Zealand with publicly funded access to modern medicines in 19 other Organisation for Economic Cooperation and Development (OECD) countries, including Australia, Great Britain and 11 European Union countries (the OECD20). Modern medicines are defined herein as: (i) comprising one or more unique molecules, and (ii) having a first registration date between 2011 and 2020. With this list of 441 modern medicines, we have evaluated New Zealand's access to medicines versus OECD peers, considering the number of medicines funded, the fraction of medicines funded across priority therapy areas and the time from in-country registration to public funding. Across all metrics, we report that New Zealand consistently features as the lowest, or second lowest, ranked country within the comparison.

Key findings are:

Patient access to modern medicines in New Zealand lags most comparable countries

• New Zealand ranks last of 20 OECD countries for the number of publicly funded modern medicines, funding 34 compared to 120 in Australia, 183 Finland, and 251 in Great Britain.

• New Zealand lags other OECD20 countries in publicly funding modern medicines across priority therapy areas: no modern arthritis or diabetes medicines were publicly funded between 2011 and 2020, and New Zealand publicly funded fewer modern medicines for cardiovascular disease and hepatitis C than all the other OECD20 countries; Portugal was the only country in the comparison to have funded fewer modern medicines for cancer and rare diseases than New Zealand.

• Less than 30% of the modern medicines registered in the OECD20 were registered in New Zealand in the last decade – 131 out of 441 medicines – and only 26% of the medicines which were registered in New Zealand were then publicly funded.

The public funding of modern medicines is significantly slower in New Zealand than in comparable countries

• The average time from in-country registration to public funding in New Zealand exceeded two years in the decade 2011-2020, almost double the average for the 20 OECD countries, and the second longest time amongst the OECD20 countries.

• Concerningly, of the modern medicines publicly funded in New Zealand in the period 2018 to 2020, only 34% were funded within two years of registration, compared to over 70% funded within two years of registration in Australia, Italy, Great Britain, Finland, France and Germany.

Source: [30] A Decade of Modern Medicines: An International Comparison 2011 – 2020

Chapter 7: Alternative medicines framework

Herbal remedies and cosmetic/medicines are largely not regulated in New Zealand, however they should not have a therapeutic statement. Also, it is important to understand the various ingredients used and its implications.

Below is a summary of information from Ministry of Primary Industries (MPI), Medsafe and NZ Customs, which cover all areas under this category.

Overview

If you are exporting herbal medicines in stable capsules, pills or powders they do not need certification or biosecurity inspection, in New Zealand. [refer to 5.10 in https://www.mpi.govt.nz/dmsdocument/1663/direct]. However, some traditional medicines are covered by the Convention on International Trade in Endangered Species (CITES) and these need permits. The following link is to CITES species (https://www.doc.govt.nz/about-us/international-agreements/endangered-species/cites-traditional-medicines/)

If the Ayurveda products fall under dietary supplements or medicines you can find their category in here Categorisation of Products (medsafe.govt.nz):
https://www.medsafe.govt.nz/regulatory/categorisation-of-products.asp

You can also find the requirements for importing dietary supplementation here, Regulation of Dietary Supplements (medsafe.govt.nz):
https://www.medsafe.govt.nz/regulatory/DietarySupplements/Regulation.asp#importing

Finally, if the Ayurveda products contain controlled substances you should refer to the NZ customs website: Prohibitions and restrictions (customs.govt.nz):

https://www.customs.govt.nz/business/import/import-prohibited-and-restricted-imports/prohibitions-and-restrictions/

The following link for MPI will explain the difference between food product and dietary supplementation: Selling and labelling supplemented food and dietary supplements | Food business | NZ Government (mpi.govt.nz)

Link: https://www.mpi.govt.nz/food-business/labelling-composition-food-drinks/health-and-nutrition-content-claims-for-food-and-drink/supplemented-food/

Food products will be covered by MPI and steps involved in importing them can be found here Steps to importing supplemented foods | Import | NZ Government (mpi.govt.nz)

Link: https://www.mpi.govt.nz/import/food/supplemented-foods/steps-to-importing/

Source: MPI

Understanding the categorisation by Medsafe

Before considering the type of herbal medicine to be imported, the NZ agent needs to access the medicine by the categorization given by Medsafe. The following points need to be considered.

Ingredients

Products categorised as dietary supplements, supplemented foods, cosmetics, or related products are not permitted to contain ingredients scheduled as Controlled Drugs under the Misuse of Drugs Act 1975 or scheduled as prescription medicines, restricted (pharmacist-only) medicines or pharmacy-only medicines under the Medicines Act 1981.

Medsafe's searchable database can be used to check whether an ingredient is scheduled under the Medicines Act. When searching for a substance in the schedule remember to check synonyms if the initial seach gives a "not found" result.

[Link: https://www.medsafe.govt.nz/profs/class/classintro.asp]

Lists of Controlled Drugs can be found in Schedules at the end of the Misuse of Drugs Act.

Purpose for use

A fundamental consideration is whether you intend your product to have a therapeutic purpose. The definition of therapeutic purpose in the Medicines Act is wide.

See details here:
http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55001.html

If a therapeutic purpose is intended for your product, and is not a medical device, it will be a medicine or related product. If you intend marketing a product as a "complementary health care product", "natural health product", or dietary supplement, you should first determine whether you intend it to have a therapeutic purpose. The following should be considered:

1. Whether the product contains a scheduled substance. A substance that has been scheduled under the medicine legislation is regarded as a medicine when provided for administration or application to humans. Scheduled substances can be searched on Medsafe's website.
2. Marketing materials, including;
    - the product label statements and claims,
    - websites,
    - depictions and context of advertising, for example advertising depicting a pharmacist selling a product to a patient could suggest it has a therapeutic purpose,
    - education sessions,
    - testimonials,
    - provision of, references to or links to information about past or present traditional use,

- social media posts and use of influencer generated material,
- television, radio, digital and print media.

3. Whether the product meets the definition of a medicine in the Medicines Act. See link: https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM54687.html

4. The expected use of the product.

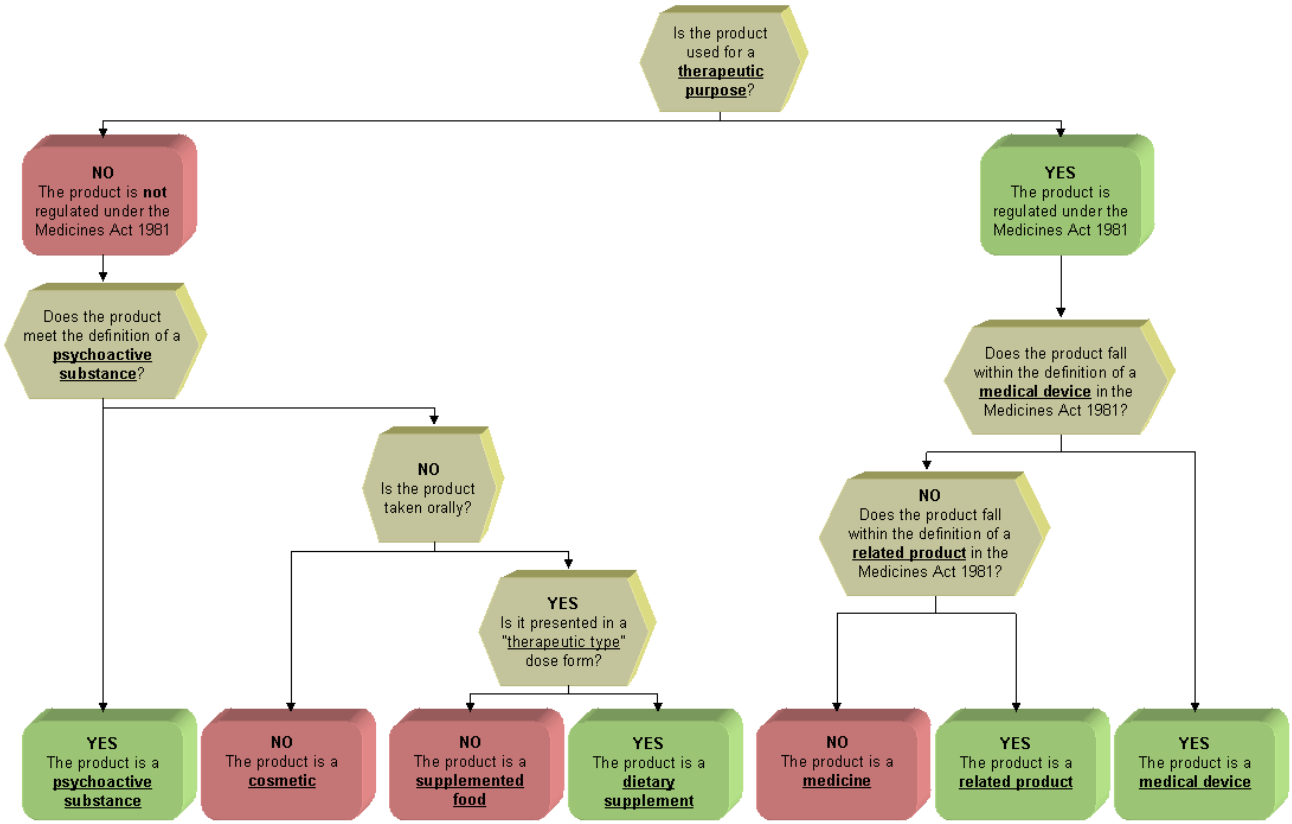
Therapeutic claims are not permitted for products supplied as dietary supplements, supplemented foods or cosmetics. Independent advice is available on whether a claim implies a therapeutic purpose. The Association of New Zealand Advertisers offers a Therapeutic Advertising Pre-vetting Service (TAPS). For a fee an adjudicator will assess labels and advertising material and advise if it is compliant with NZ legislation. TAPS also offer advice on how statements could be modified to avoid non-compliance with the Medicines Act 1981. Alternatively there are a number of regulatory affairs consultants who specialise in advertising compliance. A list is available on this web site.

TAPS website:http://www.anza.co.nz/Category?Action=View&Category_id=262

Regulatory Consultants: See chapter 10.

Another useful resource is the TAPS website. This website contains some guidelines on therapeutic claims and provides examples of claims that do not imply a therapeutic purpose.

The following can be used to determine the appropriate regulatory coverage for a product.



[See image with links here: https://www.medsafe.govt.nz/regulatory/categorisation-of-products.asp]

Source: [31] Categorisation of Products | Medsafe

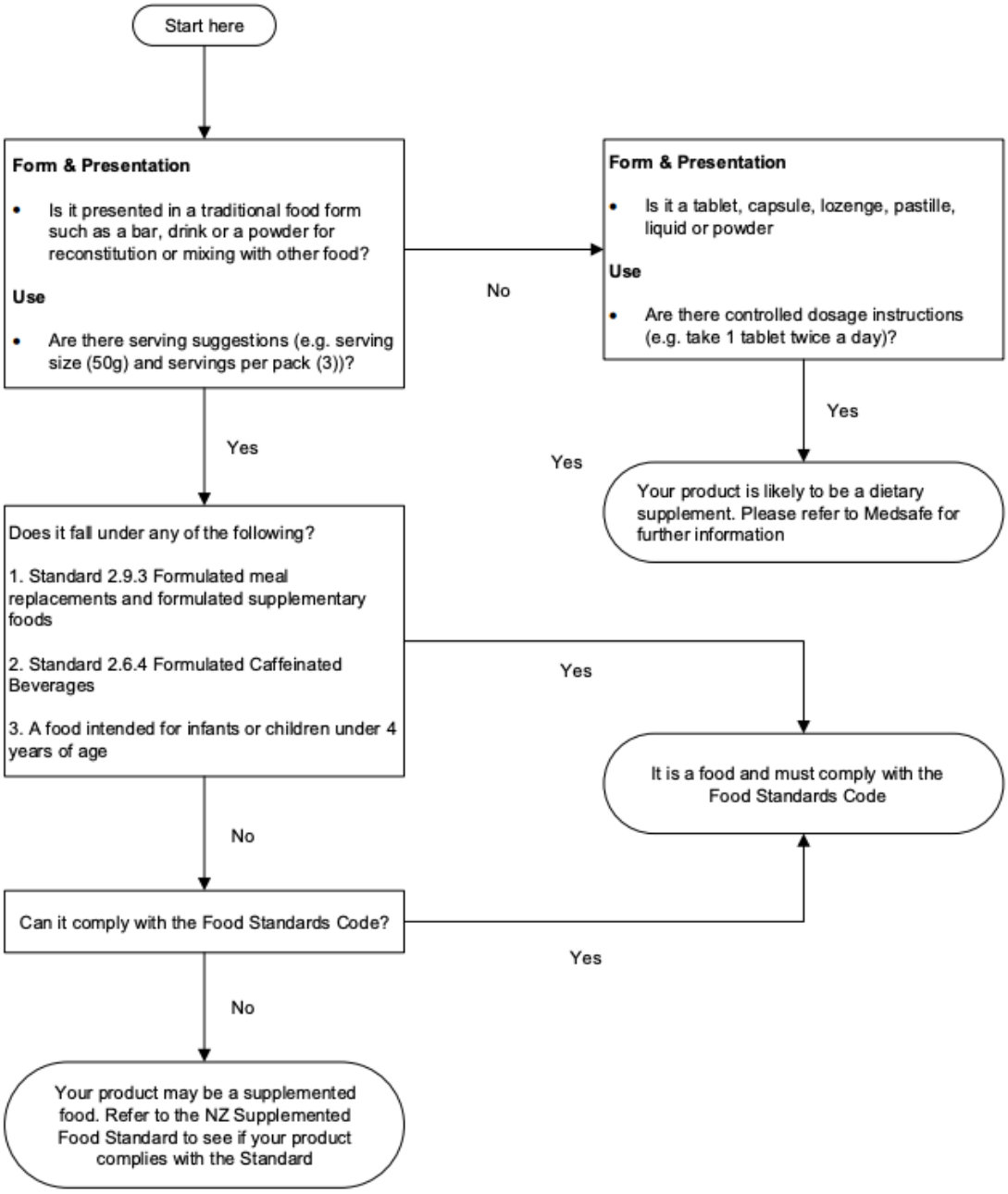
Understanding the Supplemented Food Standards

There is a detailed guide by MPI, that helps to understand the rules for the sale of Supplemented Food. It is recommened that any exporter reads and understand this thouroghly.

Supplemented Food Standard User Guide:

https://www.mpi.govt.nz/dmsdocument/13092-Supplemented-food-standard-user-guide

Flowchart to determine which requirements apply to your Product



Industry Perspective

By Dr. S. Ajit

Director, International Council of Ayurvedic Medicines & Planet Ayurveda, Auckland

Dr S. Ajit (B.A.M.S PCAS) graduated as an Ayurvedic Charya from the Government of Indian Ayurvedic College Patiala Punjabi University. He has worked selflessly as a Government Ayurvedic Medical Officer. He is a leader in the field of Ayurveda and a Panchkarma specialist, clinician and has also worked as an Ayurvedic pharmacy inspector in order to uphold and promote the Ayurvedic science in its traditional state.

Dr Ajit is the founding director of Spa Ayurda as well as Planet Ayurveda and is known for his passion towards Ayurveda and highly respected by his clients for his in-depth logical Ayurvedic interpretation and his ability to correlate Ayurvedic Principles with Western Medicine.

Excerpts from a discussion with Dr. Ajit.

Alternative medicines are generally self-regulatory.

MAF & Customs are the main agencies, that deal with the import of the herbal / plant based medicines or products. The main concern is to see if there are any prohibited items in the ingredients. There is no other barrier to entry, as long as there is no heavy metals and banned drugs. **The scope of growth in this sector is immense.**

In Australia, the sector is managed by the Therapeutic Goods Administration, however NZ does not have any such organization to provide guidance. [See https://www.tga.gov.au/ for details]

Challenges faced by the industry:

- A lot of Ayurvedic drugs are not deemed safe by the modern doctors / practitioners, because of the presence of some heavy metals in some of the herbal remedies. However, this is a misnomer, which the authorities may help to reduce. Micro-biological tests can be done and declared safe for consumption.
- Suggestion that Ministry of Ayush, Govt. of India should setup an agency for standardisation of Ayurvedic products and test them and declare ‘safe for consumption’.
- Western herbalist companies are also now marketing Ayurvedic herbs under then own brands.
- None of the Indian Ayurvedic companies are part of the Australia’s TGS license, therefore the opportunity is limited. However, their company Ayurda have been successful in getting 9 products licensed from Australia. However, this is a very expensive process and any government support will be appreciated.
- A lot of herbs available in India are being sourced from other countries like China. Ministry of Ayush can also support to make a standardisation and quality control mechanism, to support the sourcing of herbs from India.

Contact Dr. Ajit:

Parnell (Planet Ayurveda)
465 Parnell Rd, Parnell, Auckland, 1052
Phone: 09 303 0065
Web: https://www.ayurda.com/

Other sources of information

Distributors wishing to import unprocessed plant or animal material, should contact NZ Biosecurity to determine which import standards apply.

The New Zealand Customs Service is also able to advise on the requirements for commercial importation. Copies of all the New Zealand Acts and Regulations discussed above may be downloaded for free from www.legislation.govt.nz

Stored Plant Products for Human Consumption:
https://www.mpi.govt.nz/dmsdocument/1663/direct

Understanding Therapeutic Purpose:

https://www.medsafe.govt.nz/regulatory/devicesnew/1Definition.asp#purpose

Chapter 8: Industry Perspectives

We have spoken to a few industry experts, to get a more in-depth understanding of the opportunities and challenges faced by the industry. A summary of those discussions are given below.

Perspectives from a Sponsor: Pharmaco

About Pharmaco:

Pharmaco (NZ) Ltd is a New Zealand owned and operated company that was established in 1967. It provides a full range of sales and marketing services to over 20 international pharmaceutical, medical, diagnostic and scientific companies requiring representation in New Zealand and Australia, and a portfolio of over 2,500 products. Its service combines local knowledge with global expertise, to bring life-enhancing and life-saving products to this market, supported by warehousing, distribution, regulatory and administration services. Pharmaco is a leader in its field and an example of a company that has taken an entrepreneurial and innovative approach to serving the New Zealand public with vital healthcare products and services. The company's Australian subsidiary, Pharmaco (Australia) Ltd, was established in 2005 and is based out of Sydney.

Comments:

In New Zealand, the market trends do indicate that the opportunity for cost effective generic drugs will continue to grow.

However, we also believe that other global trends for example in targeted therapy (precision medicine), digital therapeutics will need to be incorporated into treatment paradigms in New Zealand. From a pharmaceutical perspective, some of the key areas in our opinion includes therapeutic segments such as Diabetes and Cardiovascular, Oncology and CNS, all of which indicate an approximate double digit growth globally on an annualized basis. Despite the necessity of generic drugs and their availability to keep the cost of overall medical treatment affordable, pharmaceutical drugs required in the aforementioned therapeutic segments are likely to be New Chemical Entities. These NCE's need to encompass not only basic oral solid dosage forms and injectables but also biological drugs created for very specific medical conditions. This therefore equates to more cost effective investments in these therapeutic areas.

Key Contacts:

Mr Avi Ramcharan – Head of Business Australia & Head of pharmaceutical business development ANZ. (Email: avi.ramcharan@pharmaco.com.au)

Mr Chandra Selvadurai – Managing Director (Email: chandra.selvadurai@pharmaco.co.nz)

Media Extract: BURDEN OF PROOF IS ON MEDSAFE TO JUSTIFY ITS EXISTENCE

by Dr. Eric Crampton | The NZ Initiative

Dr. Eric Crampton, in a recent article in The Dominion Post, gave his views on the agency Medsafe and questioned it's real purpose. The key point was that the way it is structured, it causes delays, which can be life threatening for patients. Some excerpts of this critical view are given here. Full article can be read in the link below.

Drug approval processes worldwide are costly, both in time and in money. It is important to be sure new drugs are safe. It is also important that health insurers and governments purchasing drugs know those drugs are effective.

But an approval agency that simply rubber-stamped every application it received would risk approving a lot of unsafe drugs.

And some people would be hurt or die as consequence.

But you could also imagine an agency that took half a century to approve any application. No drug would be approved unless the agency could determine, with certainty, that no adverse effects were encountered for decades after taking a drug.

Nobody outside of clinical trials would ever be hurt by a bad drug, but a lot of people would suffer and die from the conditions that those drugs could have treated.

Taking too long to approve treatment for a dangerous disease can also be an exceptionally risky choice. Especially in a pandemic.

Now imagine that Medsafe had never existed. New Zealand could rely on approvals provided by trusted regulators elsewhere.

If at least two of Australia, Canada, the United States, the UK, Singapore, the European Union, Israel, Switzerland or Japan approved a drug, it would automatically be approved here too. There are a lot of approval agencies out there. New Zealand would never be slower than the second-slowest trusted agency.

Why replicate the efforts of better resourced agencies elsewhere who are already on the task? There could be a good reason.

Delayed approvals put us at the back of procurement queues for effective Covid treatments that will be in high demand. Those treatments keep patients out of scarce intensive care beds. Delays will matter.

Pfizer's pediatric Covid vaccine was approved in America weeks ago. Millions of doses have since been administered. Canada started vaccinating kids last week. Europe approved it last week. And all seems to be going well.

At this point, the burden of proof should be on Medsafe to justify its continued existence.

What value do they provide that justifies the delay that they impose?

Medsafe could be replaced by a rule.

Any vaccine, drug, or treatment approved by at least two trusted agencies, whether fully or as emergency use authorisation, would receive matching approval here.

Courtesy: The NZ Initiative

Read full article: https://www.nzinitiative.org.nz/reports-and-media/opinion/new-opinion-140/

Chapter 9: Important Statistics & Figures

2020 – PHARMAC: Year in numbers

Combined Pharmaceutical Budget 2019/20

$1.04 billion
DHBs' combined medicines expenditure

3.74 million
Number of New Zealanders receiving funded medicines

14
Number of new medicines funded

32
Number of medicines with widened access

71,245
Estimated number of additional patients benefitting from decisions

$87.4 million
In savings reinvested in more medicines

Hospital medical devices 2019/20

17,000
Additional line items on the Pharmaceutical Schedule under national contracts

120,000+
Total line items on the Pharmaceutical Schedule under national contracts

$41 million
Value of additional medical devices under contract for 2019/20

$296 million
Total value of medical devices under PHARMAC contract

Source: [31] PHARMAC: 2020 year in review

Top 20 medicines by therapeutic groups

[gross spend - 2020]

Ranking	Therapeutic Group	Main indication	2015/16	2016/17	2017/18	2018/19	2019/20
			$m	$m	$m	$m	$m
1	Immunosuppressants	Autoimmune conditions, arthritis, transplant and biologics for cancer	$162.4	$192.1	$216.9	$247.7	$279.9
2	Antivirals	Hepatitis C	$22.1	$124.8	$84.4	$144.0	$135.1
3	Vaccinations	Vaccine preventable diseases	$92.4	$97.6	$137.1	$125.0	$124.0
4	Chemotherapeutic Agents	Cancer	$75.1	$83.3	$86.1	$93.5	$103.6
5	Antithrombotic Agents	Stopping blood clots	$63.5	$53.0	$56.0	$66.1	$75.9
6	Diabetes	Diabetes	$50.6	$53.9	$57.5	$63.4	$75.8
7	Inhaled Long-acting Beta-adrenoceptor Agonists	Respiratory conditions	$55.4	$53.0	$55.8	$58.4	$63.4
8	Antifibrinolytics, Haemostatics and Local Sclerosants	Haemophilia	$29.6	$29.2	$28.2	$33.0	$50.3
9	Endocrine Therapy	HRT	$28.2	$32.0	$35.8	$38.1	$41.2
10	Antipsychotics	Mental health	$33.3	$35.7	$37.0	$33.1	$35.6
11	Multiple Sclerosis Treatments	Multiple Sclerosis	$20.2	$24.6	$28.5	$30.1	$33.3
12	Anticholinergic Agents	Respiratory conditions	$18.4	$18.6	$22.7	$25.9	$28.8
13	Antiepilepsy Drugs	Epilepsy	$33.9	$35.5	$37.5	$36.4	$26.7
14	Diabetes Management	Blood glucose monitors and strips	$19.1	$20.6	$22.2	$24.8	$25.1
15	Antiretrovirals	HIV/AIDS	$25.4	$27.8	$30.5	$24.5	$24.0
16	Oral Supplements/Complete Diet (Nasogastric/Gastrostomy Tube Feed)	Special food	$10.8	$13.0	$15.7	$16.7	$17.9
17	Analgesics	Pain relief	$20.4	$19.2	$18.1	$17.8	$17.4
18	Agents Affecting the Renin-Angiotensin System	Blood pressure, heart failure, kidney failure and effects of diabetes	$12.3	$11.8	$12.3	$12.5	$15.5
19	Treatments for Substance Dependence	Addiction	$15.2	$14.9	$16.3	$16.4	$13.7
20	Antibacterials	Bacterial infections	$14.2	$13.9	$13.5	$12.9	$13.3
		Totals	**$802.5**	**$954.5**	**$1,012.1**	**$1,120.3**	**$1,200.5**

The data above excludes hospital purchases.

List order has been determined by top spend in the financial year 2019/20

Gross spend is shown in millions NZD and is exclusive of GST, and prior to the application of rebates and discounts.

26

Source: [31] PHARMAC: 2020 year in review

Top 20 community medicines

by number of funded prescriptions dispensed [2020]

Ranking	Medicine	Therapeutic Group	2019/20
1	Paracetamol	Analgesics	2,880,000
2	Atorvastatin	Cardiovascular	1,530,000
3	Omeprazole	Alimentary	1,480,000
4	Aspirin	Antithrombotic Agents	1,140,000
5	Amoxicillin	Anti-infectives	1,040,000
6	Ibuprofen	Analgesics	1,030,000
7	Metoprolol succinate	Cardiovascular	950,000
8	Salbutamol	Respiratory	940,000
9	Cilazapril	Cardiovascular	840,000
10	Colecalciferol	Musculoskeletal	840,000
11	Prednisone	Hormones	670,000
12	Levothyroxine	Hormones	640,000
13	Metformin hydrochloride	Diabetes	610,000
14	Zopiclone	Nervous System	590,000
15	Loratadine	Antihistamines	560,000
16	Cetirizine hydrochloride	Antihistamines	560,000
17	Amoxicillin with clavulanic acid	Anti-infectives	560,000
18	Fluticasone propionate	Respiratory	510,000
19	Codeine phosphate	Analgesics	510,000
20	Docusate sodium with sennosides	Laxatives	510,000
		Totals	**18,390,000**

Source: [31] PHARMAC: 2020 year in review

Top 20 hospital medicines

by gross spend [2020]

Ranking	Medicine	Therapeutic Group	2019/20
			$
1	Infliximab	Immunosuppressants	$41,850,000
2	Aflibercept	Immunosuppressants	$9,930,000
3	Rituximab	Immunosuppressants	$7,900,000
4	Ferric carboxymaltose	Alimentary	$6,280,000
5	Tocilizumab	Immunosuppressants	$5,360,000
6	Sugammadex	Musculoskeletal	$4,710,000
7	Clostridium botulinum type A toxin	Musculoskeletal	$4,660,000
8	Idarucizumab	Immunosuppressants	$3,330,000
9	Enoxaparin sodium	Antithrombotic Agents	$3,280,000
10	Alteplase	Antithrombotic Agents	$2,860,000
11	Levonorgestrel	Hormones	$2,450,000
12	Amphotericin B	Anti-infectives	$2,030,000
13	Amoxicillin with clavulanic acid	Anti-infectives	$1,990,000
14	Paliperidone	Antipsychotics	$1,930,000
15	Sevoflurane	Anaesthetics	$1,610,000
16	Lidocaine [Lignocaine] hydrochloride	Anaesthetics	$1,590,000
17	Olanzapine	Anaesthetics	$1,550,000
18	Lenalidomide	Oncology Agents	$1,440,000
19	Sodium chloride	Fluids and Electrolytes	$1,430,000
20	Ivacaftor	Cystic Fibrosis	$1,410,000
		Totals	**$107,590,000**

Note: Hospital data is less reliable than community data and required substantial data cleaning to produce the table above.

Source: [31] PHARMAC: 2020 year in review

Top 20 reimbursed medicines

by gross spend [2020]

Ranking	Medicine	Therapeutic Group	2019/20
			$
1	Glecaprevir and pibrentasvir[1]	Antivirals	$129,320,000
2	Adalimumab	Immunosuppressants	$98,720,000
3	Dabigatran	Antithrombotic Agents	$45,480,000
4	Pembrolizumab	Immunosuppressants	$42,160,000
5	Trastuzumab	Immunosuppressants	$35,740,000
6	Insulin glargine	Diabetes	$34,150,000
7	Pneumococcal vaccine	Vaccinations	$33,300,000
8	Etanercept	Immunosuppressants	$30,910,000
9	Human papillomavirus (6, 11, 16, 18, 31, 33, 45, 52 and 58) vaccine [HPV]	Vaccinations	$26,300,000
10	Abiraterone acetate	Oncology	$25,450,000
11	Lenalidomide	Oncology	$25,370,000
12	Budesonide with eformoterol	Respiratory	$24,970,000
13	Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B vaccine	Vaccinations	$23,120,000
14	Fluticasone with salmeterol	Respiratory	$23,040,000
15	Rurioctocog alfa pegol [Recombinant factor VIII]	Blood & Blood Forming Organs	$21,860,000
16	Rituximab	Immunosuppressants	$18,540,000
17	Rivaroxaban	Antithrombotic Agents	$16,790,000
18	Dolutegravir	Anti-infectives	$16,470,000
19	Paliperidone	Antipsychotics	$15,400,000
20	Aflibercept	Immunosuppressants	$15,170,000
		Totals	**$702,260,000**

The data above excludes hospital purchases.

Gross spend is shown in millions NZD, is exclusive of GST, and prior to the application of rebates and discounts.

This data can change as prior year adjustments are made.

Source: [31] PHARMAC: 2020 year in review

Chapter 10: Important Industry Contacts

List of Regulatory Consultants

List & Disclaimer provided publicly by Medsafe:

"Medsafe has been informed that the following people provide independent regulatory, clinical and other consultancy services to the therapeutic products sector in New Zealand (as of November 2012). These people work independently of Medsafe. Medsafe accepts no liability for the qualifications, accuracy or reliability of these consultants. No warranty or recommendation is to be assumed from the provision of this information or the omission of contact details for any other consultant."

Industry Tip: Please try to make a personal call to the companies before emailing them. Do not spam the companies given below with unsolicited emails.

Company	Services
360 Pharma Consulting Services Pty Ltd Megan Polidano Phone: +61 412864 131 Email: 360pharmaconsulting@gmail.com	Applications for new/changed medicines (Prescription and OTC) Applications for new/changed related products (Prescription and OTC) Medical devices Regulatory strategies Project management Applications for transfer/rescheduling of medicines Good Manufacturing Practice
Adjutor Healthcare Offices in Australia and New Zealand Dr Rosalie Cull PhD GAICD, Board Chair and Executive Director, Business Development Phone: +61 (0)418314763 Email: rosalie.cull@adjutor.com.au Web: https://www.adjutor.com.au	Advertising Applications for new/changed prescription medicines Applications for transfer/rescheduling of medicines Auditing Clinical trials Commercialisation strategies Competitor analysis & market insights Device vigilance and reporting Due diligence Gap analysis Good Laboratory Practice (GLP) Good Manufacturing Practice (GMP) In vitro diagnostics (IVDs) ISO 13485 Market access & reimbursement Medical affairs Medical devices Medical information Medical writing Pharmacovigilance & adverse event reporting Prescription medicines Project management Quality Management Systems - development & audits Recalls

	Regulatory submissions - local and international Regulatory submissions - medicines and devices Risk management Small to large companies, tailored services for startups Sponsorship - medicines and devices Strategy - concept to commercialisation Strategy - local and international Technical & scientific writing Training
ADVANTAGE Medical products Consulting Pty Ltd Unit 204/1013 Gold Coast Highway Palm Beach QLD 4221 AUSTRALIA Brenley M MILSOM Phone: +61 7 55224880 Mobile +61 (0) 407533048 E-mail: bmilsom@advantagempc.com.au Web: www.advantagempc.com.au	Applications for new/changed medicines Applications for new/changed related products Medical devices Good Manufacturing Practice Pharmacovigilance Advertising
All Biomedical Engineering and Regulatory Specialist Services Ruth Grant Phone: 04 5278793 Mobile: 021313169 E-mail: regrantnz@yahoo.com	Advertising Applications for new/changed related products Clinical trials Good Manufacturing Practice Medical devices
APPharma Consulting Pty Ltd PO Box 2046, Normanhurst, NSW 2076, AUSTRALIA Jeff Song Phone: +61 401 091 878 Email: jeff.song@appharma.com.au Web: www.appharma.com.au	Applications for new/changed medicines Applications for new/changed related products Applications for rescheduling of medicines Good Manufacturing Practice Advertising
AnQual GLP Laboratories School of Pharmacy, The University of Auckland A/Prof. Sanjay Garg Phone: (09) 373 7599 ext 82836 E-mail: s.garg@auckland.ac.nz Web: http://www.fmhs.auckland.ac.nz/sop/anqual/	Applications for new/changed medicines Applications for new/changed related products Medical devices Clinical Trials Good Manufacturing Practice
Archer Emery & Associates PO Box 7136, Yarralumla, ACT 2600, Australia Paul Archer, Julie Emery Phone: +61 2 6281 3873 E-mail: parcher@archeremery.com.au Web: www.archeremery.com.au	Applications for new/changed medicines Applications for new/changed related products Medical devices Clinical Trials Good Manufacturing Practice Pharmacovigilance Advertising
Avani Goswami Consulting Puninga Lane Takanini 2112, Auckland, New Zealand Mobile : 0064 221537249 E-mail : avanjit1@gmail.com	Applications for new/changed medicines Applications for new/changed related products Medical devices Good Manufacturing Practice Pharmaceutical Software Services

BELTAS™ Ltd PO Box 99 728, Newmarket 1149 AUCKLAND Gerard Dunne Phone: (09) 520 2410 E-mail: contact.health@beltas.com Web: www.beltas.com	Medical devices Clinical Trials Pharmacovigilance
BioEquitas Ltd Samantha Gray Phone: 021 1197226 E-mail: samantha@bioequitas.co.nz Web: www.bioequitas.co.nz	Dietary Supplements Food/Dietary Supplement Interface Supplemented Foods Regulations Foods Regulations and Health Claims Self-Substantiated Health Claims Dossiers Hemp & CBD Advertising inc Digital and Social Media Label Compliance & Copy Product Development – concept to commercialisation Global Market Regulatory Strategies - including: TGA Australia Complementary Medicines US FDA 21 CFR 111 Dietary Supplements Competitor Analysis & Market Insights Levels of Evidence Strategy R&D project management and cofunding Project Management & Trials Technical Troubleshooting - in process & analytical Technical & Scientific Writing Commercialisation Strategies Good Manufacturing Practice Auditing and Gap Analysis Good Laboratory Practice Analytical Methods and Validation Technical Due Dilligence Small to Large Companies - tailored services for startups
Biotech Regulatory Solutions Katy King Principal Consultant PO Box 135 Church Point NSW AUSTRALIA Phone: + 61 2 9979 2180 E-mail: katy@biotechregulatory.com.au Web: www.biotechregulatory.com.au	Applications for new/changed medicines Applications for new/changed related products Applications for rescheduling of medicines Medical devices Clinical trials Good Manufacturing Practice
Biotec Solutions Limited 35 Roscommon Road, Manukau, Auckland, Dr. Sachin Samant Phone: (09) 2789496 E-mail: Sachin@biotecsolutions.co.nz Web: www.biotecsolutions.co.nz	Good Manufacturing Practice
Brigid Glass & Associates Ltd Brigid Glass, Consultant and Coach 43 Campbell Rd, Maraetai, Auckland 2018 PO Box 281030, Maraetai Beach, Auckland 2148 Phone: +64 9 535 3119 E-mail: brigid.glass@brigidglassassociates.net Web: http://nz.linkedin.com/in/brigidglass	Medical Devices

Caroline Norwood Consulting 15 Empire Road, Devonport, Auckland 0624, NZ Caroline Norwood Mobile: +64 21 378 445 Email: c.norwood@outlook.com	Applications for new/changed medicines Medical devices
CARSL Consulting 24 Side Road, Parkhill Farm, RD10, Hastings PO Box 766, Hastings Brian Day Phone: (06) 875 0979 E-mail: carsl@xtra.co.nz Web: www.carsl.co.nz	Applications for new/changed medicines Applications for new/changed related products Medical devices Clinical Trials Good Manufacturing Practice Pharmacovigilance Advertising Device and Medicines Sponsorship
Cassandra Hogan Fontein Coaching & Consulting Services Papamoa, Tauranga Phone: 021 324 103 Email: cassandra@fonteinccs.co.nz Web: https://www.linkedin.com/in/cassandra-hogan-7975a556/	Medical Writing Technical Writing Quality Management Systems Auditing Pharmacovigilance & Adverse Event Reporting
Category 1 Pharma Consulting Pty Ltd Kingsville Victoria Australia Phone: + 61 412 800 845 Email: info@category1pharma.com Web: www.category1pharma.com	Applications for new/changed medicines Applications for new/changed related products Applications for rescheduling of medicines Medical devices Good Manufacturing Practice
Commercial Eyes Pty Ltd Level 11, 500 Collins Street Melbourne VIC 3000, AUSTRALIA Phone: +61 3 9251 0777 E-mail: : info@commercialeyes.com.au Web: http://commercialeyes.com.au/	Applications for new/changed medicines (Prescription and OTC) Applications for new/changed related products (Prescription and OTC) Medical devices Regulatory and commercialisation strategies Market access – Reimbursement strategies Market insight Pharmacovigilance & risk management Medical Information Medical Affairs Advertising Clinical development Dietary supplements Good Manufacturing Practice
Rosalind Dalefield PhD DABT DABVT Phone: 027 543 6668 E-mail: rosalind@dalefield.com Web: http://www.toxi.co.nz	Applications for new/changed medicines Preclinical trials Preclinical Good Laboratory Practice
e-MAS Medicine Advertising Service Emi Gosling (principal consultant & pharmacist) Sydney, Australia Phone: +61 (0)2 9484 3336 Mobile: +61 (0) 43 838 2505 Email: Emi@e-MAS.com.au Web: www.e-MAS.com.au	Advertising – Compliance (Consumer) Advertising – Advisory (OTC, Complementary Meds, devices) Digital and Social Media advertising Medicine Interface – Foods and Cosmetic D-T-C Medical Writing Training

Engel, Hellyer &Partners Pty Limited Level 4, 815 Pacific Highway, Chatswood, NSW 1515, Australia PO Box 5462, West Chatswood NSW 1515, Australia Dr Graeme Haley, Sandie Rooke, Ray Maio Phone: +61 2 9413 9799 E-mail: enquiries@engelhellyer.com Web: www.engelhellyer.com	Applications for new/changed medicines Applications for new/changed related products Medical devices Good Manufacturing Practice Advertising
ERA Consulting Level 3, 88 Jephson Street, Toowong, QLD 4066, Australia Mr Tristan Elliott Phone: +61 (7) 3331 3900 E-mail: info@eraconsulting.com Web: www.eraconsulting.com	Applications for new/changed medicines Clinical trials
Ethos Consulting Group 33 Old Hautere Road, Te Horo, RD2, OTAKI 5582 Mike Thompson Phone: (06) 364 3912 & (021) 364 391 Email: mike.ethos@gmail.com	Applications for new/changed medicines Applications for new/changed related products Applications for rescheduling of medicines Medical devices Clinical Trials Advertising
Erin Gentry B.Pharm(Hons), MPS, RegPharmNZ ThirtyThree, PO Box 74166, Greenlane, Auckland 1546 Email: erin@thirtythree.co.nz Web: www.nz.linkedin.com/in/eringentry3	Advertising Medical Writing and Medical Information Pharmacovigilance
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GMP Consultancy Services Limited 73- Fruitvale Road, New Lynn. Auckland Mateen Siddiqui Phone: (09) 8264474, mob 021 252 1855 E-mail: Mateen.siddiqui@yahoo.co.nz	Good Manufacturing Practice
Green Lane Coordinating Centre Level 1, 2163 Great North Road, Avondale, Auckland, New Zealand Olga Bucan Phone: (09) 820 2050 E-mail: contact@glcc.org.nz Web: www.glcc.org.nz	Clinical Trials
Hannah Temple Consulting 7 Makomako Road, Brooklyn, Wellington 6021 Hannah Temple Mobile: 021 298 9092 E-mail: hannah.temple2@gmail.com	Applications for new/changed medicines Applications for new/changed related products Medical devices Advertising
Health Audit NZ Limited PO Box 38610,Howick, Manukau 2145 Mike Thornber	Clinical Trials Good Manufacturing Practice

Phone: 0274 977833 E-mail: haudit@ihug.co.nz	
In Vivo Communications Building E, 27-29 William Pickering Drive. Albany, North Shore City PO Box 300 667, Albany, North Shore City, 0752 Lisa Sullivan Phone: (09) 448-5408 E-mail: l.sullivan@invivocom.com Web: www.invivocom.com	Applications for new/changed medicines Applications for new/changed related products Clinical Trials Advertising Medical Writing
INC Research NZ Ltd. (formerly Trident Clinical Research NZ Ltd.) PO Box 305191, Triton Plaza, North Shore 0757, Auckland Michael Gibson Phone: +64 (0)9 555 8101 Fax: +64 (0)9 478 0560 E-mail: mgibson@increasearch.com Web: www.tridentclinicalresearch.com and www.increasearch.com	Applications for new/changed medicines Applications for new/changed related products Applications for rescheduling of medicines Medical devices Clinical trials Good Manufacturing Practice Pharmacovigilance
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International Certifications Limited 30 Bishopsgate Business Centre, Bishop Dunn Pl, Botany South, Auckland Dave Evans Phone: (09) 273 4099 or 0800 ISO 9001 E-mail: admin@intlcert.com Web: www.intlcert.com	Medical devices Good Manufacturing Practice
Johner Institute Anne Arndt Informatik - Betriebswirt (VWA) Senior Consultant for technical documentation and quality management systems 221 Smiths Road 7481 Amberley Phone: +64 (0) 20 41831943 E-mail: Annett.Arndt@Johner-Institut.co.nz	Active Medical Devices Software as Medical Device Expert Opinion Software as a Medical Device Regulatory strategy development Medical Device Regulation (EU 2017/745) Quality Management Systems (ISO 13485, FDA 21 CFR 820) Good Manufacturing Practice (GMP) compliance Software Development (IEC 62304) Cyber Security

	Risk Management (ISO 14971) Usability Engineering (IEC 62366) Electric Safety (IEC 60601-x) Regulatory gap analysis (e.g., transition from EU MDD 93/42/EEC to EU MDR) Regulatory Support – Regulatory RadarRegulatory Support – Post Market Radar (MDR/IVDR-compliant post-market surveillance)
KD & A Pty Limited Level 1, 251 Hutt Street, Adelaide, South Australia Kea Dent Phone: 0011 64 823 28358 Email: kdent@kdas.com.au Web: www.kdas.com.au	Medical devices
Keene Manufacturing Solutions 59 John Gill Rd, Howick, Auckland Richard Keene Phone: (09) 534 5347, 021 278 1845 E-mail: keeneman@xtra.co.nz	Good Manufacturing Practice System and Supplier Auditing Dietary Supplements Quality System Development Recalls GMP Training
Keith Holmes Consulting 50 Sartors Avenue, Browns Bay, Auckland 0630 Dr Keith Holmes Phone: (09) 476-8082 Mobile: 027 276 8082 E-mail: keith.holmes@ihug.co.nz	Applications for new/changed medicines Applications for new/changed related products Applications for rescheduling of medicines Medical devices Clinical trials Good Manufacturing Practice Pharmacovigilance Advertising
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Maria Laitenberger Consulting New Plymouth, Taranaki, New Zealand Maria Laitenberger, B. Eng, M.A.Sc., RAC E-mail: maria.laitenberger@gmail.com Web: www.linkedin.com/in/mlaitenberger	Medical devices Quality Management Systems (ISO 13485, FDA 21 CFR 820) Good Manufacturing Practice (GMP) compliance Risk Management (ISO 14971) and Usability Engineering (IEC 62366) Labeling and Unique Device Identification (UDI) Regulatory pathway assessment for international market entry Regulatory submissions to international markets (e.g., Australia, USA, Europe, Canada) Regulatory gap analysis (e.g., transition from EU MDD 93/42/EEC to EU MDR) Technical support (e.g., biocompatibility testing, sterilization validation, packaging validation, aging testing, performance testing)

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MSR Consultancy Ltd Richard Mayfield Phone: +64 (0)9 427 9987 Fax +64 (0)9 427 9987 Mobile 021 628 379 E-mail: richard.mayfield@xtra.co.nz	Preclinical trials Preclinical Good Laboratory Practice
MTA Pharma Consulting PO BOX 1210 Glen Waverley Victoria 3150 Australia Contact: Mark Mariathas email:kmariath@tpg.com.au mobile: + 61 413325697	Applications for new/changed medicines Good Manufacturing Practice Advertising
Neon Consulting Chris Mander 40B Howe Street, Howick, Auckland 2014 Phone: 021 0249 4240 Email: neon@xtra.co.nz	Medical devices
New Wayz Consulting Ltd P.O. Box 36-496, Northcote 0748 Auckland Maurice Parlane Phone: (09) 419 8029 E-mail: info@newwayz.co.nz Web: http://www.newwayz.co.nz	Applications for new/changed medicines Applications for new/changed related products Medical devices Good Manufacturing Practice
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Pharmaceutical Solutions Limited Level 1, The Levy Building, 20 Customs Street East Britomart Business Precinct Auckland 1010 Linda Hill Phone: +64 9 379 8205 Fax +64 9 379 8244 Web: www.pharmasols.com	Advertising Applications for new/changed medicines Applications for new/changed related products Applications for rescheduling of medicines Clinical trials Good Manufacturing Practice Medical devices Medical writing Pharmacovigilance
PharmAffairs Regulatory Services Limited 29 James Evans Drive, Northcote, Auckland 0627 Pauline Harris Phone: (09) 419 9451 Mobile: 021 185 0566	Applications for new/changed medicines Applications for new/changed related products
Philippa Davies and Partners Consulting Philippa Davies BPharm, RegPharmNZ, MPS, PG DipBusAdmin Mobile: +64 21 1756590 Email: philippadavies27@outlook.com Web: https://www.linkedin.com/in/philippa-davies-16830336/	Regulatory strategic advice Market access strategic advice Advertising (prescription, OTC, dietary supplements) Compliance with industry and advertising codes of practice Medicines Classification Committee submissions Medical Affairs Business planning Business cases (BBC trained) Project Management
Quality Associates a Division of Tranzsoft Group Ltd PO Box 303-190, North Harbour AUCKLAND, Phone: (09) 448 2075 Fax (09) 448 1371 Mobile (Steve) (027) 561 2292 E-mail: steve@qai.co.nz Web: www.qai.co.nz	Good Manufacturing Practice
R-Line Limited trading as Foodaction Phill Dromgool Phone: 027 575 3348 Freephone: 0800 475 463 Email: phill@foodaction.co.nz Web: www.foodaction.co.nz	Food/Dietary Supplement Interface Dietary Supplement Formulation Dietary Supplement Labelling Supplemented Food Labelling Supplemented Food Formulation Health and Nutrition Claims TAPS Submissions Exporting of dietary supplements Self Substantiated Health Claims Novel Foods
Regulatory Concepts Pty Ltd 9/7 Anella Ave, Castle Hill, NSW 2154, Australia Dr. Helena Dickenson Phone: +61 (0) 2 9846 1900 E-mail: helenad@regcon.com.au,	Applications for new/changed medicines Applications for new/changed related products Medical devices Good Manufacturing Practice Advertising

info@regcon.com.au Web: www.regcon.com.au	
Regulatory Par Excellence Laurence Garceau Director and Principal Consultant 3/76 Merlin Street, Neutral Bay NSW 2086 Australia Phone: + 61 415 706 915 E-mail: laurence.garceau@regexcel.com Website: www.regexcel.com	Applications for new/changed medicines Applications for new/changed related products Medical devices Clinical trials
Research Associates Limited P.O.Box 17-539, Christchurch, Tony Mann Phone: 021 713671 E-mail: tony@ral-nz.com Web: www.ral-nz.com	Clinical Trials
Right Time Business Pty Limited PO Box 55 Glen Iris Victoria 3146 Melbourne Australia Roy Hardman Phone: +61 3 98855388, +61 419 100 978 E-mail: roy@righttimebusiness.com.au Web: www.righttimebusiness.com.au	Medical devices
Robert Forbes and Associates Level 1, 335-341 Glebe, Point Rd (cnr Ferry Rd), Glebe (Sydney) NSW 2037 Australia Robert Forbes Phone: +61 2 96608027 E-mail: RFAinfo@robert-forbes.com Web: www.robert-forbes.com	Applications for new/changed medicines Applications for new/changed related products Good Manufacturing Practice Advertising
Saltarelo Limited 22 Coney Hill Road, St. Clair, Dunedin Gillian Alexander Phone: 021 868 200 E-mail: Saltarelo@xtra.co.nz	Applications for new/changed medicines Applications for new/changed related products Applications for rescheduling of medicines Medical devices Pharmacovigilance Advertising
Scientific & Regulatory Solutions Sydney, Australia Contact: Jim Moshovelis Mobile: +61 406 948 498 Email: info@sciregsolutions.com.au Web: www.sciregsolutions.com.au	Applications for new/changed medicines Applications for new/changed related products Good Manufacturing Practice Quality Management / Systems Audits Regulatory & Commercialisation Strategies Dietary Supplements Food & Beverages Training
Spectrum Technology Pty Limited P.O. Box 422 Glenhuntly Victoria 3163 Australia Harry Pose Phone: +613 9578 1420 E-mail: h.pose@bigpond.com Web: www.harrypose.com	Applications for new/changed related products Medical devices Good Manufacturing Practice
Statistecol Consultants Limited 51 Woodside Rd, Mt Eden Auckland Chris Frampton	Applications for new/changed medicines Clinical trials

Phone: 0272729378 E-mail: statistecol@xtra.co.nz	
Sue Akeroyd & Associates Regulatory Consultants P.O. Box 141, Glen Iris, Victoria 3146 Australia Tel: +61-3-95090722 email: sueaker@tecspertise.com.au website: www.tecspertise.com.au	Applications for new/changed medicines Applications for new/changed related products Applications for rescheduling of medicines Medical devices
The SPD Company Pty Ltd Renée Simon Business Manager NZ and Australia Mobile: +61 402 546 792 E-mail: enquiries@theSPDcompany.com.au	Pharmaceuticals, Medical Devices and Biotechnology. New Zealand, Australia, Europe, US. Regulatory – New submissions, line extensions, WAND, Advertising review. Quality – ISO audits, QMS upgrade/implementation. Pharmacovigilance – pharmaceuticals and devices. Product development – concept development stages to commercialisation. Advertising review. Close association with Clinical Research and Reimbursement organisations.
Therapeutic Advertising pre-Vetting System (TAPS) Adjudicator 96 Hazelwood Ave, Karori, Wellington 6012 Peter Pratt Phone: (04) 938 6409 E-mail: peterpratt@paradise.net.nz Web: www.anza.co.nz	Advertising
Therapeutic Advertising p re-Vetting System (TAPS) Adjudicator 43 Tirohunga Drive, Henderson, Auckland Nigel Andrews Phone: (09) 836 2680 E-mail: nigel@rubicon.net.nz Web: www.anza.co.nz	Advertising
Therapeutic Advertising Pre-Vetting System (TAPS) Co. Association of New Zealand Advertisers Inc. 46 Braemar Road, Rothesay Bay, Auckland 0630 PO Box 35-927, Browns Bay, Auckland 0753 Maureen Roberts Phone: (09) 478 7776 Mobile: 021 68 77 60 Fax: 09 478 7731 E-mail: maureenroberts@xtra.co.nz Web: www.anza.co.nz	Advertising
Value-Based Access Pty Ltd ABN: 42 237 591 962; ACN: 161 694 195 PO Box 4369 Thornleigh, NSW 2120 Australia Eugene Salole PhD MPH	Medical devices and diagnostics: Health technology assessment (HTA) Market access strategies Value communication; Global Value Dossiers Value-based 3rd-party funding propositions 'Selling with evidence': Sales and Marketing staff

Mobile: +61-409 041 976 E-mail: esalole@valuebasedaccess.com Web: www.valuebasedaccess.com LinkedIn: https://au.linkedin.com/in/eugene-salole-ab8ab732	training in communicating product value Local research studies to demonstrate product value Stakeholder engagement
Weir Regulatory Consulting 83 Tania Ave, Palmwoods, QLD 4555, Australia Jo Weir Director and Principal Consultant Phone: +61 428 144 267 E-mail: jo.weir@weirconsulting.com.au Website: www.weirconsulting.com.au	Applications for new/changed medicines Applications for new/changed related products Applications for rescheduling of medicines Medical devices Good Manufacturing Practice Advertising Medical writing
Yasmeen & Associates 4 Chapel Court, Doncaster, Victoria 3108, Australia Dr Dilruba Yasmeen Phone: +61 3 9848 4770 E-mail: dyasmeen@bigpond.net.au	Applications for new/changed medicines Applications for new/changed related products

List of important companies in New Zealand's pharma sector

Note: This is not an exhaustive list. Contact details may change from time of publication.

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Roche	98 Carlton Gore Road Newmarket Auckland 1023 Phone:+64 9 523 9400 Freephone:0800 656 464 Email:nz.info@roche.com
GlaxoSmithKline	Pharmaceuticals and Vaccines For general enquires: Telephone: 0800 808 500 or +64 9 367 2900 Madeleine Breckon, Head of Communications, ANZ Email: madeleine.s.breckon@gsk.com
Pfizer	Pfizer New Zealand Level 1, Suite 1.4 Building B, 8 Nugent Street Grafton Auckland 1023 GENERAL ENQUIRIES: +64 9 354 3065 0800 699 276 https://www.pfizer.co.nz/contact-us
Janssen	Address: 507 Mount Wellington Hwy, Mount Wellington, Auckland 1060, New Zealand Phone: +64 9 588 1343 or free call within New Zealand: 0800 800 806 Fax: +64 9 588 1398
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PharmaBrokers	www.pharmabroker.co.nz 106 Bush Road, North Harbour, Auckland Ph: 09 415 5050
Crombie & Price	Auckland Support Office (Marketing) Unit 1 / 666 Dominion Road Balmoral Auckland, New Zealand Phone +64-3-434-8311 http://www.crombie-price.co.nz/contact-us.html

Chapter 11: Pharma Manufacturing in India

Introduction

The Indian pharmaceuticals market ranks 3rd globally in terms of market share by volume and 14th by value. Also, India is the largest exporter of generic medicines in the world as it contributes to 20% market share by volume.

The Indian pharmaceuticals manufacturing capabilities were demonstrated during the COVID-19 pandemic. India, being the largest producer of vaccines in the world, provided life-saving drugs and vaccines globally. Till 16th March 2022, India had supplied 167 million vaccine doses to 98 countries.

India is a world leader in the production of anti-reteroviral drugs - meeting 80% of the global demand of anti-reteroviral drugs for HIV-AIDS. Similarly, India holds a very strong position in the supply of other vaccines (BCG, DPT, Measles), for instance, the country fulfills 90% of the global demand for the measles vaccine.

What is the potential of Pharma manufacturing in India?

Growth and opportunities in the Indian pharmaceuticals sector

Infrastructure

- Indian government has implemented the *Ayushman Bharat Programme* (ABP) that has a dual focus on – building healthcare infrastructure and increasing penetration of health insurance. Under ABP, highly equipped wellness centres will be created at primary, secondary and tertiary levels. Further, India is moving towards universal health coverage with nearly 70% of the Indian population covered under the ambit of ABP, state government schemes, and private health insurances. The increase in access to healthcare infrastructure is an opportunity for the Indian pharma industry to diversify investments in the sector.
- There is a strong emphasis by the Government of India to set up Biosafety Level-3 (BSL-3) laboratories. The objective is to increase capacities in clinical research for targeting new pathogens.
- To promote translational research, 9 biotechnology parks have been established by the Department of Biotechnology. Research institutes in the biotech parks work in close collaboration with numerous healthcare start-ups to develop and commercialise the technology.
- Under Government of India's *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP), quality generic medicines are provided at affordable prices to everyone, thus, increasing the access to equitable healthcare facilities. As on 31st January 2022, the pharmacies had been increased to 8,675 that covers all 739 districts of India. By 2025, India aims to

further increase these pharmacy stores to 10,500. Under the PMBJP scheme, affordable 1451 drugs and 240 surgical instruments are provided in these pharmacies stores.

- With India transitioning to 4th industrial revolution – digital healthcare, precision medicine, telemedicine, and artificial intelligence; new research and manufacturing pipelines are being developed, scaled, and deployed. Therefore, combination of the moonshot sectors – pharmaceuticals and information technology – will result in a strong foundation for the development of advanced digital technologies in the healthcare sector.

Foreign direct investment (FDI)

- The Economic Survey 2021-22 highlighted that FDI inflows in the pharma sector has increased by 200% in the 2020-21 vis a vis the previous year.
- With ever-increasing FDI inflows, the Indian pharmaceuticals market is expected to reach US$ 130 billion by 2030, with the compounded annual growth rate of ~12%.

New segments for the drug development

- Indian continues to hold strong position in the manufacturing of generic formulations and vaccines, but future opportunities are going to arise in new sub-segments – biosimilars, biologics, orphan drugs, cell and gene therapy, and new chemical enitites. Therefore, major Indian pharmaceutical companies have already established research and manufacturing units to diversify their product portfolio into the new sub-segments. The diversification of export products will impart access to global supply chains.
- With large number of US-FDA and WHO-GMP compliant manufacturing plants, India is rightly placed to embark in the era of new drug products. For instance, more than 52 companies have ~200 biosimilars in the manufacturing pipeline.

Human capital

- With ~64% of the population in the working age group, demographic dividend favors the creation of large, highly-skilled workforce.
- According to All India Survey on Higher Education (AISHE) 2019-2020, India has nearly 2.24 million students in STEM streams. A large pool of technology-oriented workforce will push growth of the pharma industry.
- India has highly-qualified workforce in pharmacy and information technology sectors. Also, the National Education Policy 2020 focuses on increasing access to advanced digital technologies.

Epidemiological factors

- Covid-19 has necessitated the need for setting up research units in predictive epidemiology. The increasing disease burden either due to the lifestyle changes or the emergence of new pathogens resulting in pandemics or epidemics, have created an environment in which the governments are realigning their healthcare strategies.
- Thus, the Government of India is making huge strides to create an enabling ecosystem for research and development (please see policy framework below).

What is the policy framework for foreign pharma companies to manufacture / collaborate with Indian companies?

Investing guidelines

The Government of India has initiated structural reforms to increase foreign direct investment (FDI) in India. In pharmaceuticals, under the automatic route (without government approval), up to 100% FDI is allowed in greenfield projects and up to 74% FDI in brownfield projects. The investments are also expected in the pharmaceutical clusters (Figure 1).

In these clusters, specific or customised incentives are also provided by the state governments for the promotion of the pharmaceuticals industry. Pharma companies are given various tax and other subventions to set up manufacturing units in the special economic zones (SEZs) or pharmaceutical clusters.

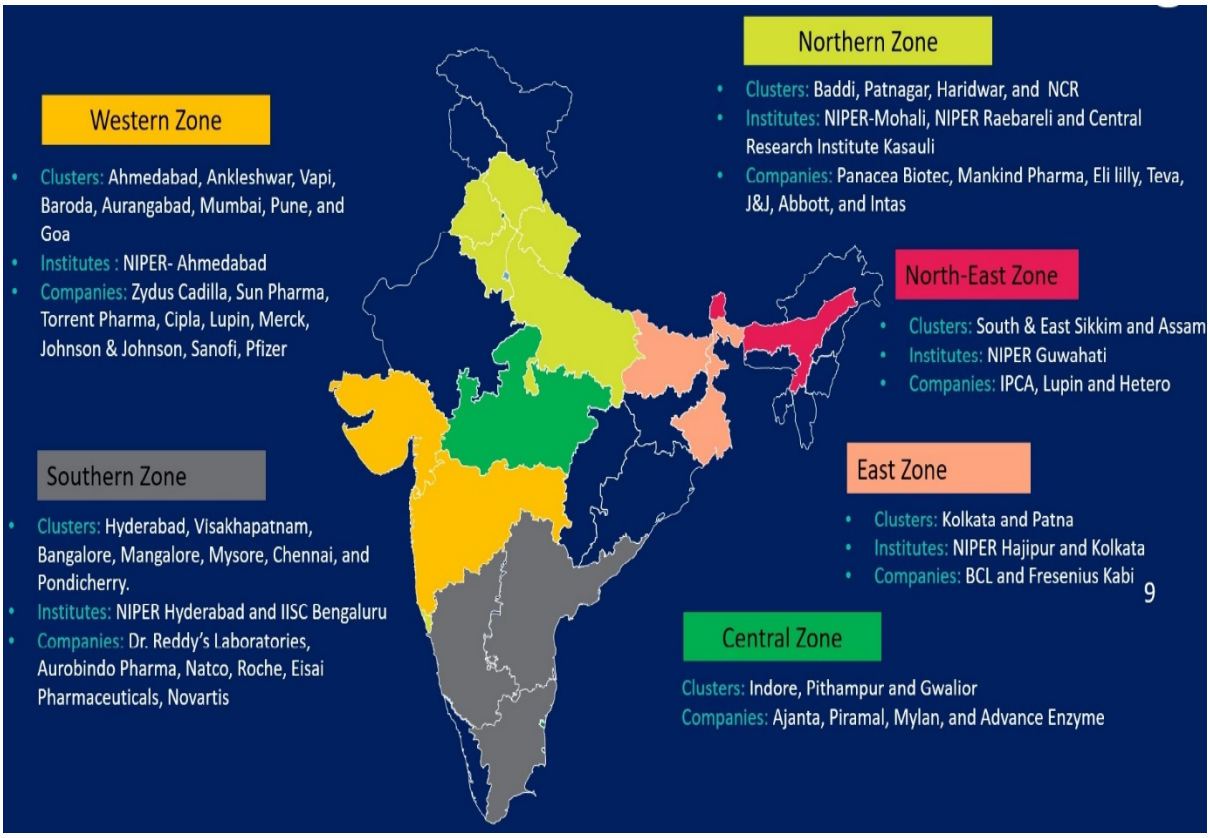

Figure 1. Pharmaceutical clusters of India.

Policy frameworks for the promotion of manufacturing in India

The primary aim of recent policy frameworks has been to promote R&D in the country.

- Department of Pharmaceutical's recently launched Draft R&D and Innovation Policy (2021) promotes interdisciplinary collaborations to develop translational skills and start-up ecosystem. The draft policy also focuses on strengthening regulatory framework, incentivizing investments, and creating a facilitatory ecosystem for innovation.
- The approach paper to draft National Medical Devices Policy 2022 focuses on strong collaborations for developing accessible, affordable, and sustainable innovations in the medical devices sector.
- Also, under the New drugs and Clinical trials rules 2019, fast-track regulatory approvals are granted. This significantly brings down the cost of clinical trials in India as compared to developed countries.

Apart from the above policy frameworks, the Government of India has initiated multiple reforms to further streamline investment opportunities in India, thus, increasing the ease of doing business.

- *National Single Window System:* It is a digital platform that facilitates the application of ~500 regulatory approvals and services across 32 central government ministries and departments, including 14 states and union territories of India.
- *Bonded Warehouse and Manufacturing Facilities*: It allows for greater competitiveness in the export market by allowing for zero-rated import of inputs when the final goods are earmarked for export.
- *Reducing compliance burdens*: In the recent years, more than 22,000 compliance have been reduced with ~13,000 compliances simplified.

Are there any incentives?

The Government of India provides several incentives for the promotion of manufacturing in India. Similarly, various specific or customised incentives are also rolled out by state governments. The manufacturers of pharmaceutical goods registered in India can avail benefits of the following schemes:

1. Production-linked incentive (PLI) scheme

- PLI includes US$ 1 billion incentive linked to sales to augment the manufacturing of key starting materials (KSMs), drug intermediates (DIs), and active pharmaceutical ingredients (APIs).
- It also includes US$ 2 billion incentives for the manufacturing of biopharmaceuticals, complex generics, orphan drugs, cell and gene therapies, and phyto-pharmaceuticals.

These incentives have been implemented to further increase manufacturing capabilities of India.

2. Bulk drug parks scheme

- The US$ 400 million scheme emphasises on the promotion of drug parks for the manufacturing of bulk drugs.
- The scheme will reduce import dependence along with decreasing cost of bulk drugs in the country.

3. State government schemes

- States have specific policies for the promotion of life sciences industry. For instance, the Government of Telangana had implemented the Life Sciences Policy (2015-2020), which significantly contributed to the development of biotechnology and pharma ecosystem in the state. Telangana's Genome valley, in Hyderabad, now contributes to ~33% of the supply of vaccines to the globe.
- Similarly, the Government of Gujarat has published the Biotechnology Policy (2022-2027) to impart impetus to the burgeoning biotechnology sector.
- These policies aim to provide specific incentives for promotion of the industry in the state. For instance, incentives pertaining to land, capital, and power are given by the state governments – further boosting manufacturing capabilities of the Indian pharmaceuticals industry.

Support provided by Make in India / Invest India team.

Project Development Cells (PDCs) have been constituted in 29 ministries and departments of the Government of India.

Invest India is mandated by the Government of India to handhold investors in their investment journey in India.

A PDC has been established between Department of Pharmaceuticals and Invest India. The PDC works to address grievances related to the implementation of the PLI scheme and any other investment plans, among various other initiatives listed below:

- **Facilitate investors:** PDCs help investors in getting regulatory/land approvals or address grievances pertaining to different schemes launched by the Department of Pharmaceuticals, Government of India.
- **Develop policy initiatives:** In close discussion with the Department of Pharmaceuticals and industry leaders, regular webinars and brainstorming sessions are conducted to further streamline the investment landscape in the pharma sector.

Content Courtesy: Invest India Team

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