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Regulatory Requirements for Registration of Pharmaceuticals in New Zealand

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ABSTRACT

The present work highlights the legislative and regulatory environment for the registration and marketing of therapeutic products in New Zealand. Despite a relatively small population, New Zealand maintains an advanced healthcare system and pharmaceuticals market. Most of the 40 to 50 new active substances which are produced by the pharmaceutical industry each year are submitted for approval in New Zealand and approval times for these medicines are comparable to, or faster than, economically developed countries. There are several manufacturers of generic medicines who service the internal market, as well as export to Australia, the South Pacific, and the growing pharmaceutical markets of Southeast Asia. As with many countries, the problem currently facing New Zealand is the extent of the pharmaceuticals budget at a time when the government is placing increasing constraints on public health expenditure. In the long run, the continued access of patients to new and innovative products through the regulatory approval process may be dependent on arrangements achieved between the pharmaceutical industries and funding agencies. Medicines and Medical Devices Safety Authority (Medsafe) is the pharmaceutical regulatory authority in New Zealand. This study explores the format and data requirements for applications for Ministerial consent to distribute new and changed medicines that need market approval and provides an overview of the regulations that tend to the approval of the medicinal product.

INTRODUCTION:

New Zealand is an island country in the southwestern Pacific Ocean. The country geographically comprises two main landmasses – that of the North and South Islands – and numerous smaller islands, stretching 1,700 kilometers (over 1,000 miles) across the South Pacific Ocean, midway between the equator and the South Pole. It covers 266,000 square kilometers (104,000 square miles). New Zealand is organized into 11 regional councils and 67 territorial authorities for local government purposes. Nationally, executive political power is exercised by the Cabinet, led by the Prime Minister. Queen Elizabeth II is the country's head of state and is represented by a Governor-General. New Zealand is heavily dependent on international trade, particularly in agricultural products. Exports account for a high 24 percent of its output, making New Zealand vulnerable to international commodity prices and global economic slowdowns. Its principal export industries are agriculture, horticulture, fishing, forestry, and mining. Its major export partners are Australia, the United States, Japan, China, and the United Kingdom[1].

a) Government: Constitutional Monarchy with a Parliamentary Democracy

b) Population: 4,327,944 million

c) Capital: Wellington

d) Largest city: Auckland

e) Currency: New Zealand dollar (NZD)

f) Official languages: English, Māori, NZ Sign Language

g) GDP (nominal): Total $161.851 billion Per capita $36,648

Health System in New Zealand:

The healthcare system of New Zealand has undergone significant changes throughout the past several decades. From an essentially fully public system in the early 20th century, reforms have introduced market and health insurance elements primarily in the last three decades, creating a mixed public-private system for delivering healthcare.

In 2005, New Zealand spent 8.9% of its GDP on health care or US$2,403 per capita. Of that, approximately 77% was government expenditure. In a 2010 study, New Zealand came last in a study for the level of medication use in 14 developed countries and also spent the lowest

amount on healthcare with US$2510 ($3460) per capita, compared to the United States at US$729.

OVERVIEW OF REGULATORY ENVIRONMENT FOR THERAPEUTIC PRODUCTS

The Minister of Health has overall responsibility for the regulatory control and funding of therapeutic products in New Zealand, though authority is routinely delegated to the Director-General of Health and the Health Funding Agency (HFA) [2].

History:

The Department of Health was formed in 1903 by the merging of other government departments. Its structure remained relatively static even when the 1938 Social Security Act was passed where the New Zealand government took a larger role in health purchasing. The department remained actively involved in policy as opposed to purchasing. By the 1970s problems had appeared in the health system. The high growth rate in hospital expenditure was occurring at a time when the economy was slowing down. Thus, the government was unable to sustain funding for this growth.

This led the health system to undergo a series of changes over 20 years from the 1980s. During the 1990s the National government attempted to streamline the system with a series of reforms such as separating the government purchasing and provision of health care services. During this time the department was renamed the Ministry of Health. District Health Boards were formed in 2001 as a subsidiary organization of the Ministry. As of 2005, 21 different District Health Boards exist. These are responsible for hospitals and funding some health provisions in their respective areas.

THERAPEUTIC PRODUCTS LEGISLATION

The medicines legislation controls products used in humans for therapeutic purposes. A product is considered to be intended for a therapeutic purpose if a therapeutic claim is stated or implied in the product labeling or promotional material, or where the active ingredient(s) has a pharmacological action. All medicines marketed in New Zealand must comply with the legislative requirements in force at the time. The principal pieces of legislation that regulate the use of therapeutic products in humans are the Medicines Act 1981 and the Medicines Regulations 1984 and their respective amendments.

The Medicines Act 1981 imposes controls on the manufacture and distribution of medicines and related products, the conduct of clinical trials, and the advertising and sale of medicines, related products, and medical devices. The Act also details provisions for enforcement of the legislation. The Medicines Regulations 1984 specify the detailed requirements for medical advertisements, prescribing and dispensing, licenses, data sheets, and the manufacture, packing, labeling, and storage of medicines and related products.

The objectives of the study are:

1. To encompass the regulatory structure of the Therapeutic Legislative Authority (Medsafe).
2. To enlist different procedures followed in the registration of medicines in New Zealand.
3. To focus on different regulations involved in regulating the quality of medicines.
4. To enlist the timelines of evaluation of different applications.

Review of Literature:

Mike Thompson[2] in his book explained about, details of the legislative and regulatory environment for the registration and marketing of therapeutic products in New Zealand. Despite a relatively small population, New Zealand maintains an advanced healthcare system and pharmaceuticals market. Most of the 40 to 50 new active substances which are produced by the pharmaceutical industry each year are submitted for approval in New Zealand and approval times for these medicines are comparable to, or faster than, in many Organisations for Economic Cooperation and Development (OECD) countries.

Alex Sundakov*et al.*, [3] have given an overview of Public policy concerning the funding of pharmaceuticals needs to balance cost containment objectives with optimization of health outcomes. Most countries employ a range of price and expenditure containment techniques. New Zealand is unique, however, in using the capping of the pharmaceutical budget and tendering for exclusive supply to reduce prices as the cornerstone of its approach[3].

Gabriel T.L[4] in his review explained, The New Zealand health system is publicly funded. Although there are private hospitals, they do not have emergency departments and exist primarily as an avenue for getting non-urgent specialty procedures. Most people do not have private insurance and go onto a waiting list at public hospitals to get their specialist appointments arranged or their surgical procedures are done.

Espicom Business Group[5] in their report mentioned about, Low growth potential in New Zealand's pharmaceutical market will attract risk-averse investors. However, we note that regulatory delays in funding new medicines will hinder patients' access to pharmaceuticals, constituting a downside risk for drug companies looking to sell their products in the country.

Headline Expenditure Forecasts:

Pharmaceuticals: NZD1.35bn (US$1.07bn) in 2011 to NZD1.36bn (US$1.04bn) in 2012; +1.2% in local currency and -2.7% in US dollar terms.

Healthcare: NZD19.34bn (US$15.29bn) in 2011 to NZD19.93bn (US$15.14bn) in 2012; +3.0% in local currency and -1.0% in US dollar terms.

Medical Devices: NZD814mn (US$644mn) in 2011 to NZD832mn (US$632mn) in 20 12; +2.2% in local currency and -1.8% in US dollar terms.

Risk/Reward Rating: New Zealand was ranked 10th out of 18 pharmaceutical markets surveyed in the Asia region in Q1 13. Its score is dragged down by a low industry rewards score, due to its small and relatively low-growth potential market, and a low industry risks score because of its regulatory processes. In terms of Rewards, New Zealand has rated highly thanks to a stable economic and political environment and developed regulatory regimen.

Study parameters:

The following information is taken into consideration in the conduct of the present study.

i. Introduction to New Zealand regulatory authority.
ii. Content and format for e-CTD submission in New Zealand.
iii. Dossier requirements for the registration of medicine in New Zealand.
iv. Registration process in Medsafe.

NEW ZEALAND REGULATORY AUTHORITY (MEDSAFE):

Medicines and Medical Devices Safety Authority (Medsafe) is the pharmaceutical regulatory authority responsible for the approval of new therapeutic products and the regulatory control of products being marketed. Medsafe is a business unit of the Minister of Health (MOH). PHARMAC is the New Zealand Government’s pharmaceutical management agency. It evaluates medicines and determines which ones it will fund.

Medsafe operates independently of PHARMAC, though the two agencies cooperate on matters of mutual interest. The role of PHARMAC is included because the funding situation is becoming an increasingly important factor for companies deciding whether or not to apply for regulatory approval of new therapeutic products in New Zealand. Hence, both Medsafe and PHARMAC play a key role in the availability and utilization of products[2].

Medicines and Medical Devices Safety Authority (Medsafe):

a) Organizational Structure:

Medsafe has around 60 staff operating out of two offices, with centralized administrative functions. Medsafe's management structure is shown in the following organization chart[6].

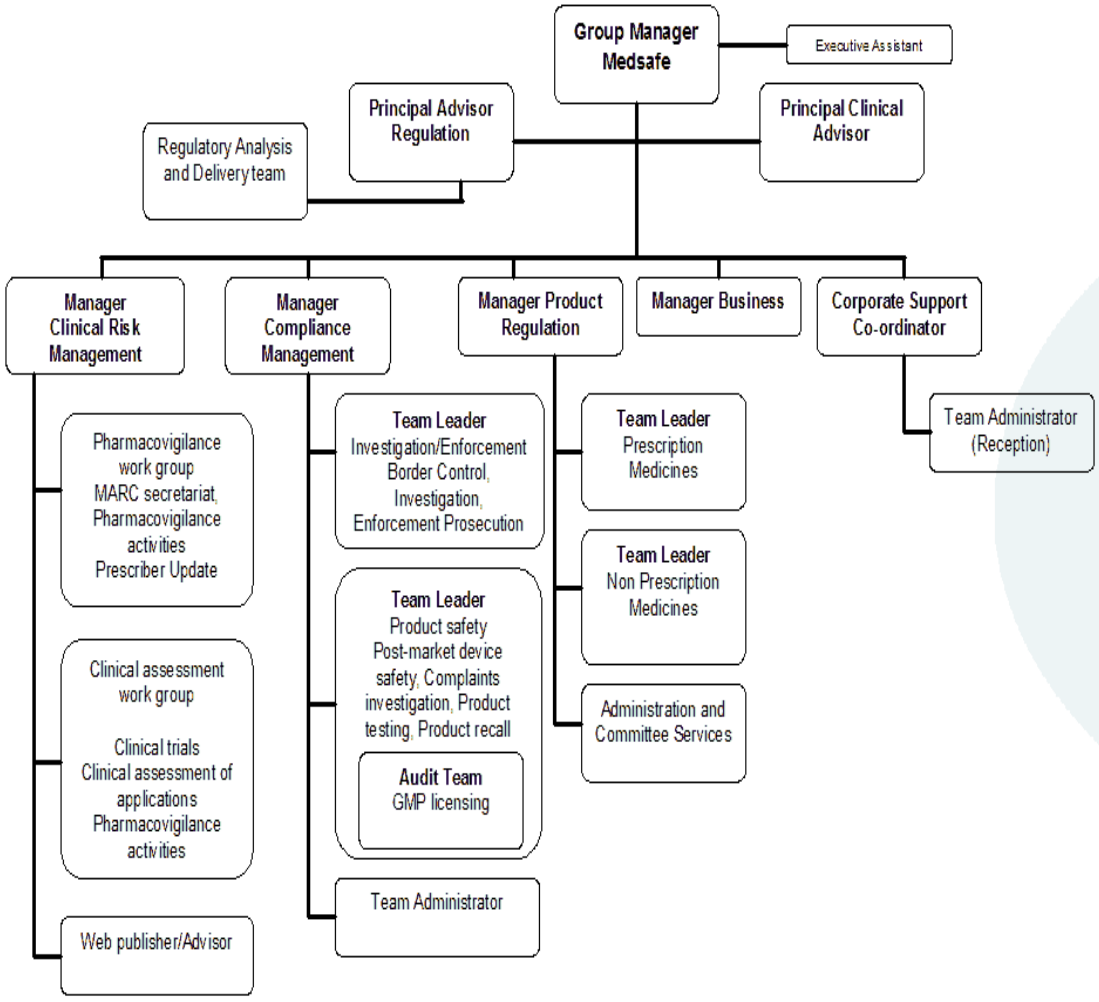

Figure 1: Organizational Structure of Medsafe

b) Statutory responsibilities and accountabilities:

- The regulatory responsibility of Medsafe is to administer the Medicines Act 1981 and parts of the Misuse of Drugs Act 1975, and their accompanying Regulations.

- The objective of the medicines legislation is to manage the risk of avoidable harm associated with the use of medicines. The legislation is designed to ensure that:

✓ Medicines conform to acceptable standards of safety, quality and efficacy.

✓ Personnel, premises and practices used to manufacture, store and distribute medicines comply with requirements to ensure the continued conformity of the products to those standards until they are delivered to the end-user.

✓ Information about the selection and safe use of medicines is provided to consumers and prescribers of medicines.

c) In carrying out its functions, Medsafe is accountable to:

- The Minister of Health through delegations and the Purchase Agreement between the Ministry of Health and the Minister of Health.

- The Ministry of Health for regulatory activities and policy advice or public good activities funded by the Crown.

- The pharmaceutical industry those activities which are funded by fees collected from the industry.

d) Regulatory framework:

- Medsafe's mission is accomplished by applying a framework that ensures benefits in the use of therapeutic products while managing potential risks. Ensuring that the therapeutic products available in New Zealand are those which can be expected to have greater benefits than risks if used appropriately, is achieved through a pre-marketing approval system and post-marketing surveillance.

- New medicines and related products cannot be marketed in New Zealand without the consent of the Minister of Health (or delegated authority). Changed medicines and related products cannot be marketed without the consent of the Director-General of Health (or delegate). 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 to Medsafe for evaluation before consent can be granted.

e) The internal structure of Medsafe:

Medsafe consists of three operational teams: Evaluation Team, Compliance Team, Business Development, and Support Team

i. The Evaluation Team provides advice to the Minister and Director-General of Health on the quality, safety, and efficacy of medicines and related products which are proposed for distribution in New Zealand.

ii. The Compliance Team ensures that therapeutic products and persons involved in their manufacture, distribution, and use comply with legislative requirements.

iii. The Business Development and Support Team develops policy, strategic direction, and business opportunities for Medsafe to oversee medicine classification and pharmacovigilance and provides prescribers, pharmacists, and consumers with information about the safe use of medicines and medical devices.

PHARMAC (Funding Agency):

PHARMAC is the New Zealand Government's pharmaceutical management agency. It evaluates medicines and determines which ones it will fund. It first receives and considers the evidence submitted by the applicant. Finally, after prioritizing the application, PHARMAC then negotiates pricing with the manufacturer, reprioritizing the application based on the outcome of those negotiations.

The initial application must include full information on the medicine's Medsafe registration, the condition the medicine is for, and the pharmaceutical itself. The application covers pharmacology and epidemiology, and the medicine's effectiveness, safety, and potential impact on the health sector. The application must also provide information on pricing, the market, patents, and lead times. All this must be submitted to PHARMAC ten weeks before the monthly board meeting where it will be considered.

Based on the summary the board makes a preliminary economic assessment and identifies areas in which it requires objective clinical advice on the application. If PHARMAC requires clinical advice, it refers the application to the Pharmacology and Therapeutics Advisory

Committee (PTAC), who's Board meets every three months. In some cases, the application will be referred to one of the specialist PTAC subcommittees, which meet every five months.

A cycle of negotiations between PHARMAC and the manufacturer then begins. An assess-prioritize-negotiate process repeats until, if the application is successful, a preliminary agreement is reached. PHARMAC then consults with the health sector on the proposal and takes this feedback into account before submitting the final proposal to the PHARMAC board. The PHARMAC may request fast-tracking of evaluation of certain new medicine applications where significant cost savings may result from the availability of the medicines concerned on the New Zealand market[2].

THERAPEUTIC PRODUCTS

Categorization of Therapeutic Products:

Products used for the therapeutic purpose are categorized as medicines, related products, herbal remedies, or medical devices. Definitions of other categories (e.g., cosmetics, dietary supplements, herbal remedies, etc.) are also provided in the legislation and official standards and are further described in various guidelines[7].

1) Medicines:

✓ In practical terms, a product is a medicine if it is administered to humans primarily for a therapeutic purpose. Most, but not all, medicines have a pharmacological effect.

✓ The therapeutic purpose is defined as the treatment, diagnosis, and prevention of a disease or the modification of a physiological function. It also includes cleaning, soaking, or lubricating contact lenses, inducing anesthesia, or effecting contraception intrauterine devices (IUDs) contraceptives (e.g. diaphragms) are devices. The only products that are regulated as medicines, but are not administered to humans, are pregnancy test kits.

✓ The consent of the Minister is required before a new medicine can legally be distributed in New Zealand. Medicines that are also Controlled Drugs are controlled under the Medicines Act 1981 and the Misuse of Drugs Act 1975 and associated Misuse of Drugs Regulations. The following are not medicines and the Minister's consent is not required for their distribution in New Zealand:

- Substances used in dental surgery for filling dental cavities (these are medical devices).

- Non-medicated bandages and other surgical dressings (these are medical devices).
- Medicated dressings where the medication has a curative function that is not limited to sterilizing the dressing are medicines by legislation.
- Radioactive materials are used for therapeutic purposes.

2) Related Products

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 is required before a new related product can legally be distributed in New Zealand.

Examples of related products include the following:

- Non-liquid products for external use (e.g. pastes, gels, and powders) containing not more than 1000 ppm (0.1%) of fluoride.
- Non-liquid products for external use containing more than 1000 ppm (0.1%), but not more than 1500 ppm (0.15%), of fluoride that includes the following warning statements on the label:

✓ "do not swallow", and

✓ "do not use this product in children 6 years of age or less.

- Antidandruff shampoos.
- In addition, the following have traditionally been treated as related products:

✓ Antiseptic throat lozenges (Fungicidal lozenges are restricted medicines.)

✓ Antiseptics are used for cleaning wounds, cuts, abrasions, stings, insect bites, and superficial burns.

3) Herbal Remedies

- It is a medicine that does not contain a prescription, restricted or pharmacy-only medicine, and consists of a substance derived from plant material that has been dried or crushed (or derived through any other similar process). It may also be an aqueous or alcoholic extract of the dried or crushed plant material or a mixture of that material with another inert substance.

- Ministerial consent is not required for the distribution of a herbal remedy that is sold or supplied without any recommendation as to its use and the labeling complies with the requirements of Section 28 of the Medicines Act, whereas Ministerial consent is required for the distribution of a herbal remedy which is sold with a recommendation for use for a therapeutic purpose.

4) Homeopathic Remedies

- A homeopathic remedy is prepared under the principle of homeopathy in which the active ingredient to be administered is in a concentration not more than 20 parts per million, and the remedy is labeled only with the name of the active ingredient, trade name (if any) and a statement that it is a homeopathic remedy does not normally require Ministerial consent before distribution.

- The product label or associated advertising material must not contain therapeutic claims or indications for use. A homeopathic remedy that is labeled or advertised with claims as to its therapeutic purpose is medicine and is subject to the full control of the Medicines legislation.

- Sterile homeopathic preparations intended for injection or administration to the eyes are regarded as medicines and therefore subject to the full control of the Medicines legislation.

5) Medical Devices

- A medical device is any device, instrument, apparatus, etc. used primarily by humans for a therapeutic purpose. This includes bandages and surgical dressings provided they are not medicated with a therapeutic agent (if medicated, they are medicines). New Zealand and Australia have a joint reporting system for adverse reactions to medical devices.

6) Cosmetics with a Therapeutic Purpose

- In general terms, a cosmetic is a product used to cleanse, protect or beautify the hair or skin. The following types of products, when sold without any therapeutic claims and not containing any substance listed in the First Schedule of the Medicines Regulations 1984 (and amendments) are considered to be cosmetics, and the Minister's consent for distribution is not required for their distribution:

* Antiperspirants

* Deodorants

* Insect repellents
* Dusting powders
* Sunscreen and suntan preparations
* Cleansers for normal or blemished skin
* Moisturizers for normal, sunburnt, or wind burnt skin
* Hair conditioners
* Astringents and skin toners
* Agents to assist in the fading of spots, pimples, and blemishes.
* Antiseptics for generalized, all-over use, on the body and not on broken skin
* Solutions that are bathed in to relax the body.
* Anti-wrinkle and anti-aging products have a superficial cosmetic effect and not a physiological effect.
* Cosmetics must not be advertised as making basic underlying changes to the skin such as cellular changes.
* Sunscreens are currently categorized as cosmetics and do not require approval or Ministerial consent before marketing. Companies are encouraged to market only sunscreens that comply with the Australian/New Zealand Standard AS/NZS 2604:1998.

7) Dietary Supplements

- Dietary supplements are controlled under the Dietary Supplement Regulations 1985. In practical terms, a dietary supplement is an edible substance, in a controlled dosage form, which is intended to supplement the intake of substances normally derived from food. A product marketed as a dietary supplement may not be promoted for therapeutic purposes. Companies wishing to make therapeutic claims for such products must apply for consent to distribute the product as a medicine or related product.

Table no 1: Consent to distribute the product as a medicine or related products.

S.No	Type of Therapeutic product	Minister consent required
1	Medicines	✓
2	Related products	✓
3	Herbal remedies	*
4	Homeopathic remedies	×
5	Medical devices	✓
6	Cosmetics	×
8	Dietary supplements	*

***** Ministerial consent is required depending upon the therapeutic purpose of the product.

MEDICINES

Classification of Medicines:

- The Medicines Classification Committee (MCC) is a ministerial advisory committee to make recommendations to the Minister of Health regarding the classification of medicines as prescription medicines, restricted medicines, or pharmacy-only medicines:

i. Prescription Medicine:

- Prescription medicines may be supplied only on the prescription of an authorized prescriber as defined in the Medicines Act 1981. They may also be used by a registered member of another specified health profession when permitted in the First Schedule to the Medicines Regulations 1984 or amendments.

ii. Restricted Medicine (or Pharmacist-Only Medicine):

- Restricted medicines may be sold without a prescription, but the sale must be made by a registered pharmacist, in a pharmacy, and details of the sale must be recorded.

iii. Pharmacy-Only Medicine:

- Pharmacy-only medicines may only be sold in a community or hospital pharmacy, or a shop in an isolated area that is licensed to sell that particular medicine. The sale may be made by any salesperson.

- Medicines of these classification categories are listed in the First Schedule to the Medicines Regulations 1984, which is a list of active ingredients grouped under their respective classifications. Medicines not listed in the classification schedules are deemed to be unclassified and are referred to as General Sale Medicines. These medicines may be sold from any outlet.

Registration as medicine with Medsafe:

Medsafe is responsible for regulating therapeutic products in New Zealand on behalf of the Minister of Health. Before a manufacturer can distribute a therapeutic medicine in New Zealand it must be registered with, reviewed, and approved by Medsafe. There are two types of application[9]:

I. New Medicines Applications (NMAs) are for products that have not yet been approved or have been materially changed, with different ingredients, strengths, or dose forms.

II. Changed Medicine Notifications (CMNs) are for previously approved products that are now intended to be used to treat something different.

Table 2: Medsafe Performance Targets for the Evaluation of Applications (in working days)

Phase	**New H-NMAS**	**New I-NMAS**	**New L-NMAs**	**CMNs**
Receipt and acknowledgment of application	Application acknowledged within **5 days** of receipt	Application acknowledged within **5 days** of receipt	Application acknowledged within **5 days** of receipt	Application acknowledged within **5 days** of receipt
Initial	295 days	Initial evaluation completed within **30 days** of acknowledgment of application	Initial evaluation completed within **20 days** of acknowledgment of application	Initial evaluation completed within **20 days** of acknowledgment of application
Evaluation of additional data		Applicant's first response evaluated within **20 days** of receipt	Applicant's first response evaluated within **15 days** of receipt	Applicant's first response evaluated within **15 days** of receipt
Ongoing requests for additional information and evaluation of responses-No performance target				
Consent process	Consent notice submitted for publication in *Gazette* within **5 days** of the decision to recommend approval	Consent notice submitted for publication in *Gazette* within **5 days** of the decision to recommend approval	Consent notice submitted for publication in *Gazette* within **5 days** of the decision to recommend approval	N/A
Evaluation and the finalizing of the data sheet- No performance target				
Total time application under Medsafe action	**300 days**	**60 days**	**45 days**	**40 ays**

ABBREVIATED EVALUATION PROCESS

A. Introduction:

The basis for the abbreviated evaluation procedure is the review of regulatory evaluation reports rather than a review of the medicine dossier. Therefore, the quality and availability of evaluation reports should be a fundamental consideration.

- The abbreviated evaluation process does not apply to new lower-risk new medicine applications or Changed Medicine Notifications (CMNs).

- This is particularly important if the product details sought for registration rely upon an overseas evaluation report for a variation in product details. The abbreviated evaluation process is intended to be a simpler and quicker process than the standard evaluation process. This is reflected in the application fee.

- Medsafe reserves the right to re-route abbreviated evaluation applications to the standard evaluation process if the application does not fulfill the intent of this process.

- To be eligible for the abbreviated process the application must be for an intermediate-risk or high-risk medicine that:

✓ is approved by one of a range of recognized regulatory authorities before submission of an application to Medsafe; and

✓ Was approved by a recognized regulatory authority in 2001.

✓ The abbreviated evaluation process may be applied to medicines approved by the EMEA (via the centralized procedure).

B. Application and evaluation process:

Applicants seeking consent to distribute new higher-risk or intermediate-risk medicines have two options.

➢ Standard evaluation process

➢ Abbreviated evaluation assessment

✓ During the abbreviated evaluation process, Medsafe will ascertain the following.

➢ Whether the submitted international regulatory evaluation reports are of a sufficient standard to allow an abbreviated assessment to occur.

➢ Whether any product details are not supported by evaluation reports and approval documents.

➢ Whether any aspect of the product poses any safety issues if used in the New Zealand market, and will determine whether the product requires evaluation against any Medsafe-specific evaluation requirements.

C. Recognized regulatory authorities:

For the abbreviated evaluation process, Medsafe recognizes the following regulatory authorities:

✓ Australian Therapeutic Goods Administration (TGA)

✓ United States Food and Drug Administration (FDA)

✓ Health Products and Food Branch of Health Canada

✓ Medicines and Healthcare products Regulatory Agency (MHRA)

✓ European Medicines Evaluation Agency (the centralized procedure only)

✓ EU member states (decentralized or mutual recognition procedure only).

A. Required documentation:

Applications must describe the product and the history of the product's evaluation and approval by the recognized regulatory authority for new medicines**.** The following information must be submitted.

1) A cover letter requesting that the application be evaluated using the abbreviated process.

2) A complete Module 1 was completed specifically for New Zealand registration.

3) Applicants should use the NMA form posted on the Medsafe website.

4) A complete dataset as required by the Medicines Act 1981 and the NZRGM, consisting of Modules 2, 3, 4, and 5 (as applicable). This dataset must be in CTD format.

5) A table of contents for the dossier to provide easy reference to the submitted information. This table will need to include information under at least the following headings.

a. Date of the event.

b. Event description (e.g. type of application, request for further information).

c. A brief description, in chronological order, of correspondence with the recognized regulatory authority.

6) A copy of the approval letter approved product and evaluation reports details, including any attachments from the recognized regulatory authorities.

7) A copy of requests for information issued by the recognized regulatory authority that has approved the product and the responses to such requests.

8) Evidence, if required, of the relevance of the submitted biostudy reference product to the New Zealand market reference product in line with the NZRGM.

9) Finalized labeling and packaging copy from the recognized regulatory authority and proposed New Zealand labeling and packaging.

10) A copy of the drug substance specifications applied by the drug product manufacturer and a copy of the drug product release, and expiry specifications approved by the regulatory authority.

B. Application requirements:

The sponsor of an eligible product may apply for provisional consent to distribute medicine and must include:

1. The name and contact details of the product sponsor.
2. The name under which the medicine will be distributed.
3. The qualitative and quantitative particulars for each ingredient in the product.
4. A description of the dose form of the medicine.
5. Details of the dosage, frequency of use, and route of administration or method of use. The purposes for which the medicine is recommended to be used and the claims to be made in respect of the medicine.
6. Evidence of approval and availability of a product containing the same active ingredients, in the New Zealand market, before the date five years before the provisional consent application is made.
7. Evidence that the product is made in a GMP-licensed facility, such as a copy of a GMP license specifying the manufacture of the applicable product at the specified manufacturing site.
8. Evidence of routine use of the product in New Zealand hospital practice
9. Endorsement of the continued use of the medicine by a hospital drug committee and details of the volume of the medicine used over the preceding three-year period.

10. Certification that the product labeling complies either with the New Zealand requirements or with the requirements of the recognized overseas regulatory authority and with New Zealand Misuse of Drugs legislation (if applicable).

11. Certification (for Category 1 products only) that the data sheet (if required) for the product is identical to that approved by the recognized regulatory authority.

12. Certification (for Category 1 products only) that the product supplied in New Zealand is identical to that approved by the recognized overseas regulatory authority.

C. Fees:

Requests for fee waivers may also be submitted with applications submitted for the abbreviated process for provisional consent following section 61A of the Medicines Regulations 1984. Medsafe will make a case-by-case determination of whether or not this application fee may be partially waived for the public good.

New Medicines Application (NMA) Fees	
Type of application	***Fee***
New higher-risk medicine containing one or more new active substances	88,875
Any other new higher-risk medicine	43,875
New intermediate risk medicine – prescription Medicine	43,875
New intermediate risk medicine – non-prescription Medicine	7,650
New lower-risk medicine	7,650
Additional dose form – higher-risk medicine – Grade 1 or 2	43,875
Additional dose form – intermediate-risk prescription medicine – Grade 1 or 2	43,875
Additional dose form – intermediate-risk non-prescription medicine – Grade 1 or 2	7,650
Additional dose form – lower-risk medicine – Grade 1 or 2	7,650
New combination pack containing 2 or more currently approved products	3,200
Additional names, strengthens, flavours and classifications notified at the same time as the parent application	0
The following fees apply when the additions are subsequent to the parent application	
Additional name - Grade 1	720
Additional name - Grade 2	1,440
Additional classification (with/without new name)	720
Additional strength - Grade 1	2,160
Additional strength - Grade 2	2,880
Additional strength - Grade 3	5,760
Additional strength - Grade 4	18,000
Additional strength - Grade 5	27,000
Additional flavour or type of sweetening	1,440

New Medicines Application (Abbreviated Evaluation Process) Fees	
Type of application	***Fee***
New higher-risk medicine containing one or more new active substances	33,750
Any other new higher-risk medicine	33,750
New intermediate risk medicine – prescription medicine	16,875

Additional names, strengthens, flavours and classifications must be notified at the same time as the parent application	0

Figure no 2: Fees payable under the Medicines Act 1981

SUMMARY:

❖ The present medicines legislation is dated and no longer meets all of the needs for regulation of therapeutic products in New Zealand. Medsafe, the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), is the agency responsible for the approval of new therapeutic products and the regulatory control of products being marketed.

❖ Medsafe is a business unit of the MOH and is based in central Wellington. The funding of prescribed products that are subsidized by the government is the responsibility of the Pharmaceutical Management Agency Limited (PHARMAC). The information that is to be submitted under these drug submission types is based on the ICH CTD and the Medsafe regulatory framework for drug approval.

❖ In line with its risk assessment approach to regulatory control, and to facilitate the administrative processing of applications, Medsafe categorizes NMAs into three types, as follows:

- New Higher-risk Medicine Application (NMA-H)
- New Intermediate-risk Medicine Application (NMA-I)
- New Lower-risk Medicine (NMA-L)

❖ The medicines legislation controls products used in humans for therapeutic purposes. Products used for a therapeutic purpose can be categorized as:

1. Medicines
2. Related products
3. Herbal remedies
4. Medical devices

❖ Medsafe is responsible for the registration of medicines that are manufactured in New Zealand, and has two application processes:

a) New Medicine Application

b) Changed Medicine Application

❖ Medsafe provides standard requirements for Generic Prescription Medicines.

❖ It gives concise information on the manufacture and quality control of active ingredients, excipients, and finished products.

❖ New Medicines are assessed based on three priority assessments.

1. Significant clinical need.
2. Significant potential cost savings.
3. Medicines Manufactured for New Zealand for export.

❖ The major advantage of the New Zealand registration procedure for new medicines – Has a fast-track approval process that reviews regulatory reports rather than a medicine dossier.

CONCLUSION:

This study explores the format and data requirements for applications for Ministerial consent to distribute new medicines that need market approval and provides an overview of the regulations that tend to the approval of the medicinal product. The funding by the health authority would serve as a base of attraction for the pharmaceutical manufacturers and will be playing a major role in the setting up of the facilities in New Zealand. The export sector of the region is a favorable destination for the exporters owing to its export potential and dependence on the exported medicines from New Zealand by other countries.

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