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REVIEW ARTICLE

Useni Reddy Mallu et al, The *Experiment, 2013, June, Vol.11. (3), 690-705*

PHARMACUETICAL DRUG PRODUCTS APPROVAL PROCEDURE IN AUSTRALIA

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ABSTRACT

This article is written only for the educational purposes. The objective of this article is to guide the industry about the Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products. TGA is the administrator for approval of medicines and devices in Australia. As per the TGA act all the medicines are classified in to prescription, non-prescription medicines and export only medicines. Prescription medicines are classified in to three categories like, Category-1; Category-2 and Category-3 type applications.

Keywords: Australian Drug Approval, Therapeutic Goods Administration (TGA), Prescription Medicines, Complimentary Medicines, Over the Counter Medicines, Pharmaceutical Drug Products

INTRODUCTION

The Therapeutic Goods Administration (TGA) is the regulatory agency for medicines, medical devices, blood and tissues in Australia. Australian Register of Therapeutic Goods (ARTG) is a database and contains the information of therapeutic goods. Figure-1 represents the complete organogram of TGA

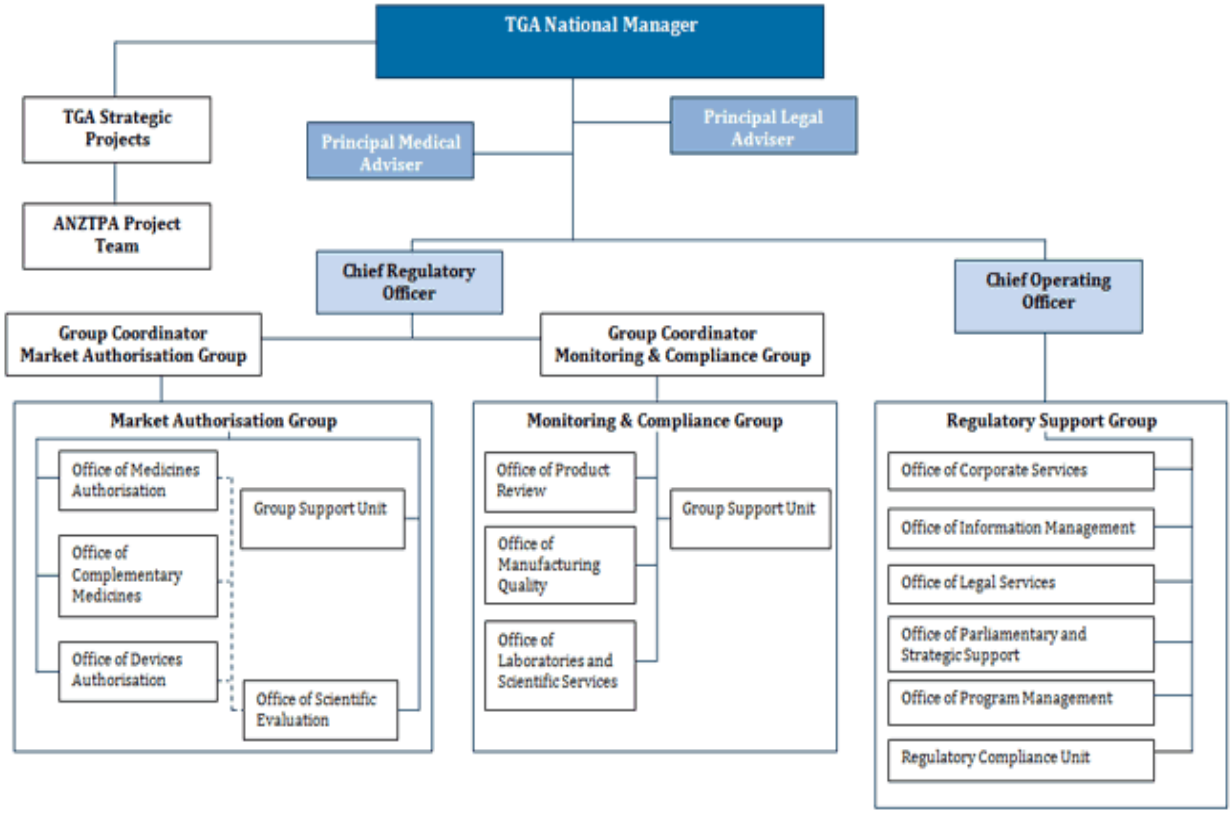

Figure-1: Organogram of Therapeutic Goods Administration (copied from official website)

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Australian TGA advisory committee:

Australian therapeutic goods administration has different advisory committees for medicines and devices evaluation, approval and monitoring the activities of safety and efficacy. The TGA advisory committees are,

1. Australian Drug Evaluation Committee (ADEC): Prescription medicines
2. Adverse Drug Reactions Advisory Committee (ADRAC)
3. Medicines Evaluation Committee (MEC) : OTC medicines
4. Complementary Medicines Evaluation Committee (CMEC): Complementary medicines
5. Therapeutic Devices evaluation Committee (TDEC): Medical devices
6. National Drugs and Poisons Scheduling Committee (NDPSC)
7. Therapeutic Goods Committee (TGC)

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)

The *SUSMP*, is established under Section 52D of the *Therapeutic Goods Act 1989*, and is a compilation of the decisions made under Section 52D of the same Act. The *SUSMP* should be read in conjunction with the *Scheduling Policy Framework* (SPF) of the National Coordinating Committee on Therapeutic Goods. It is a document used in the regulation of drugs and poisons in Australia. It is produced by the National Drugs and Poisons Scheduling Committee (NDPSC), a committee of the TGA. As per the TGA act, The SUSDP has scheduled the all substances, their classifications, labeling and packaging requirements. The classification takes into account a substance's toxicity profile, pattern of use, indications, product formulation and dosage, potential for abuse and need for access. Medicines listed in the SUSDP are considered high-risk.

Table-1: Standard for the uniform scheduling of drugs and poisons

SCHEDULE DETAILS	DESCRIPTION
Therapeutic drugs	
2 (S2) Pharmacy Medicine	Non-prescription medicines sold in pharmacies. A pharmacist's advice may be required for their safe use.
3 (S3) Pharmacist only Medicine	Non-prescription medicines for supply by a pharmacist only.
4 (S4) Prescription Only Medicine	Prescription only medicines for supply by a pharmacist only.
Agriculture, Domestic and Industrial	
5 (S5) Caution; 6 (S6) Poison and 7 (S7) Dangerous Poison	
Therapeutic drugs	
8 (S8) Controlled Drug	Substances that require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.
Medical or Scientific Research	
9 (S9) Prohibited Substance	Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law. except when required for medical or scientific research

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THERAPEUTIC GOODS

As per the TGA act regulations all type of goods are divided in to medicines and devices. Medicines are again divided in to

i. Prescription medicines,
ii. Non-prescription medicines and
iii. Export only medicines.

The detailed categories are represented in figure-1.

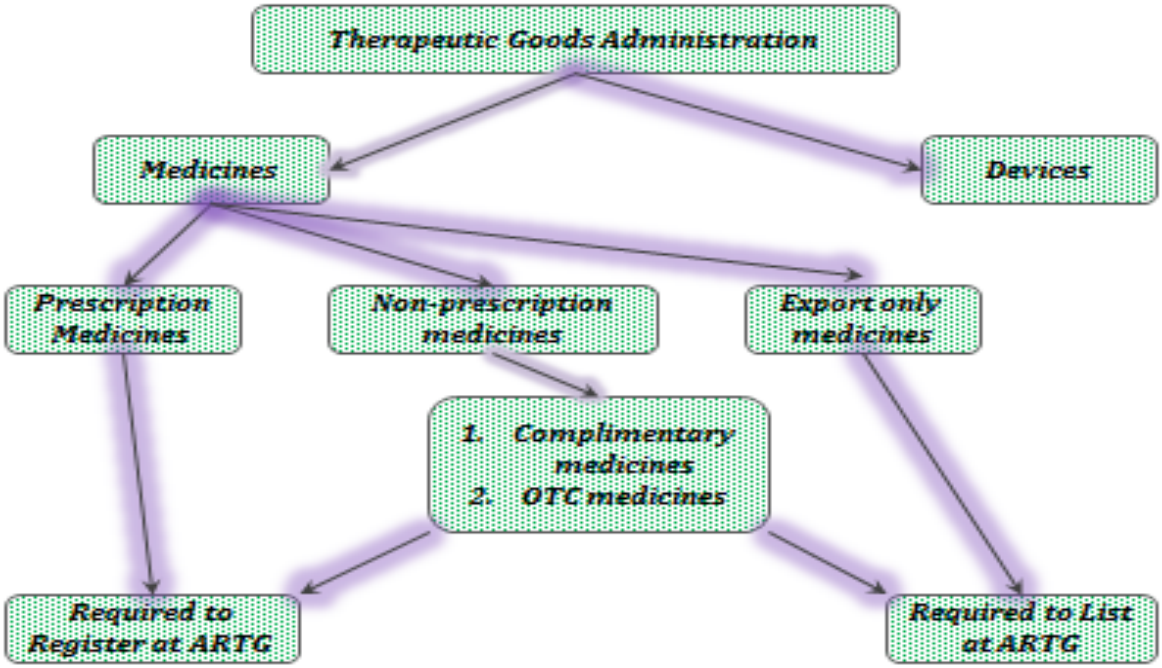

Figure-2: TGA medicines and Devices

i. Prescription medicines (PM):

Prescription medicines are high-risk medicines that contain ingredients described in Schedule 4 and 8 or Schedule 9 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and are available by prescription only.

- The Drug Safety Evaluation Board (DSEB) evaluates the majority of prescription medicine applications. **Ex:** insulin for diabetics.
- All prescription medicines must be registered in TGA.

ii. Non-prescription medicines (NPM):

NPM are classified in to two categories that are,

a. OTC Medicines
b. Complementary medicines

a. OTC medicines

An over the counter (OTC) medicine is a therapeutic good mentioned in Part 3 of Schedule 10 of the Therapeutic Goods Act 1989 that does not meet the criteria for mention in Schedule 4, 8 or 9 of the Poisons Standard. **Ex:** Antiseptics, Sunscreens

- The Non-prescription Medicines Branch (NPMB) is responsible for evaluating OTC medicines.

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- The majority of OTC medicines are non-prescription registered medicines and examples include mild analgesics, cough/cold preparations, and antifungal creams.

b. Complementary medicines (CM):

- CM is consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and for traditional use. Complementary medicines are also known as 'traditional' or 'alternative' medicines. **Ex:** Vitamins, minerals, herbals, and homoeopathic products.
- The Office of Complementary Medicines (OCM) is responsible for the evaluation of complementary medicines at the TGA.
- Complementary medicines can be regulated as listed medicines.

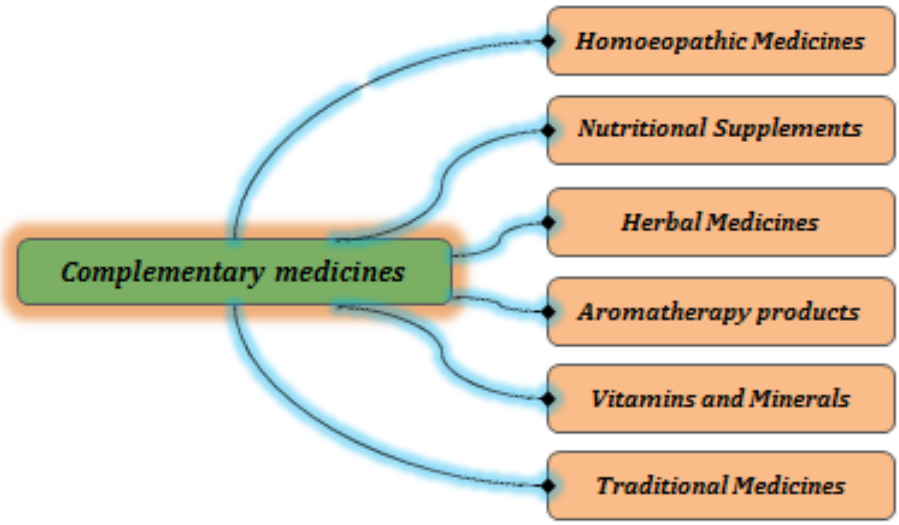

Figure-3: Sub group medicines in Complementary medicines

Complementary medicines are generally available for use in self-medication by consumers and can be obtained from retail outlets such as pharmacies, supermarkets and health food stores. While the majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, many are indicated for maintaining health and wellbeing, or the promotion or enhancement of health.

c. Export only medicines:

Products containing substances, quantities of substances or labels without mandatory warning statements required for listing for supply in Australia which would require registration for domestic supply will be assessed under Section 26 of the Act.

Ex:

1. Commercial export of medicines
2. Export of medicines for donation or humanitarian purposes
3. Export of human body fluids/ tissue
4. Export of medical devices
5.

TGA USER FEE

The applicant needs to pay the fee for drug product submission, evaluation and annual fees to the TGA. The fees details are included in Schedule 9 of the *TGA regulations*. All type of fees values may change from time to time. The annual fee is not payable for *low volume, low value* products (Applicant must apply to the TGA, providing a declaration that the wholesale turnover is low volume and

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low value). The fee will be depends on the type of application like, new chemical entity, extension of indications, generic application etc. the fee will be depends on the following type of application.

1. The new chemical entity
2. Extension of indications
3. Major variations in the applications
4. New generic product
5. Additional trade name
6. Minor variation
7. Variation to a register entry involving the evaluation of quality information
8. Changed to the PI involving the evaluation of data
9. Changes to product information where no evaluation is required
10. Changed to consumer medicine information
11. Variations to a register entry involving the evaluation of only quality information and clinical, non-clinical or bio-equivalence data, but not included in another fee category
12. Notification of self-assessable changes
13. Safety related notification
14. Testing and provision of advice, requested from pharmaceutical benefits program, prior to listing on pharmaceutical benefits listing program

MEDICINES REGISTRATION OR LISTING

As per the TGA regulations high risk medicines should be registered and low risk medicine need to list at ARTG for marketing the drug products in Australian region. Registered and listed medicines categories are mentioned in table-1. After approving the medicine, it can get the assigned number either an AUST R number (registered) or AUST L number (listed medicines).

AUST R medicines:

Table-1: Registered and Listed Medicines

Registered medicines
➢ Registered medicines are assessed by the TGA for quality, safety and efficacy.
➢ All prescription medicines are registered.
➢ Most over-the-counter medicines are registered.
➢ Some complementary medicines are registered.
Listed medicines
➢ Listed medicines are assessed by the TGA for quality and safety but not efficacy.
➢ Some over-the-counter medicines are listed.
➢ Most complementary medicines are listed.

They include all prescription only medicines and many over-the-counter products such as those for pain relief, coughs and colds and antiseptic creams. It will assessed for safety, quality and effectiveness.
Prescription only medicines do not display their purpose on the label as the decision for using those lies with a doctor; however, over-the-counter medicines must have a purpose displayed.

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AUST L medicines:

They are used for minor health problems and are reviewed for safety and quality. They include sunscreens over SPF4 and many vitamins, mineral, herbal and homoeopathic products. A purpose must be included on the label.

Complementary Medicines Listing:

Complementary medicines are listed through Electronic Listing Facility (ELF) by creating the E-business account. Office of Complementary medicines will evaluate the complementary medicines. After creating the E-business account, then applicant need to give the complete information of the product like, reference product details, product name, type, formulation details including dosage form, route of administration, container type, container volume, container closure, maximum single dose, maximum daily dose, minimum weight of each dosage, components and their quantities, manufacturer's details including whether the manufacturer is Australian or an overseas manufacturer. If applicant is overseas manufacturer then need to submit the clearance ID or GMP Reference number. When you submit your application, it becomes available for view on the ARTG listing. A random selection of submissions is subject to review by the OCM. They may request to see information relating to the presentation, advertising materials, or information about product manufacture. Listing procedures are clearly represented in figure-4.

OTC Medicines Listing:

OTC medicines are listed by using e-business account with OTC Products Application Lodgment (OPAL) system. In order to create a listing of OTC medicines need to submit the following information,

- Applicant reference details and Product name and any relevant export names
- Product type, Dosage form, route of administration, container type and closure and Pack size
- Payment exemption number (if you received one from the TGA)
- Label name and export names (if applicable)
- Proposed therapeutic indications

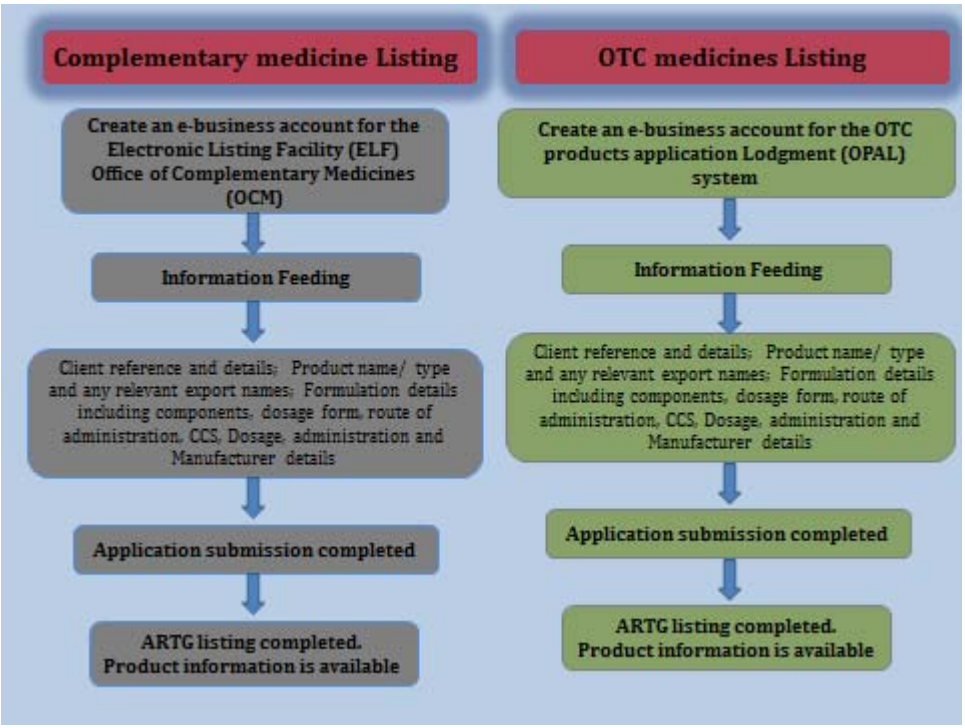

Figure-4: Listing procedure of Complementary and OTC medicines at ARTG

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- Ingredients including whether the ingredient is active, an excipient, active homeopathic or a proprietary ingredient
- Components and their quantities
- Manufacturer's details including whether the manufacturer is Australian or an overseas manufacturer. If an overseas manufacturer is selected then clearance ID or GMP reference number must be provided
- Indication of supporting data that has been sent to the TGA including chemical, stability, toxicological, clinical or other data.
- Printed labeling and packaging materials.
- When you submit your application, it becomes available for view on the ARTG listing.

The detailed process flow has represented in figure-4.

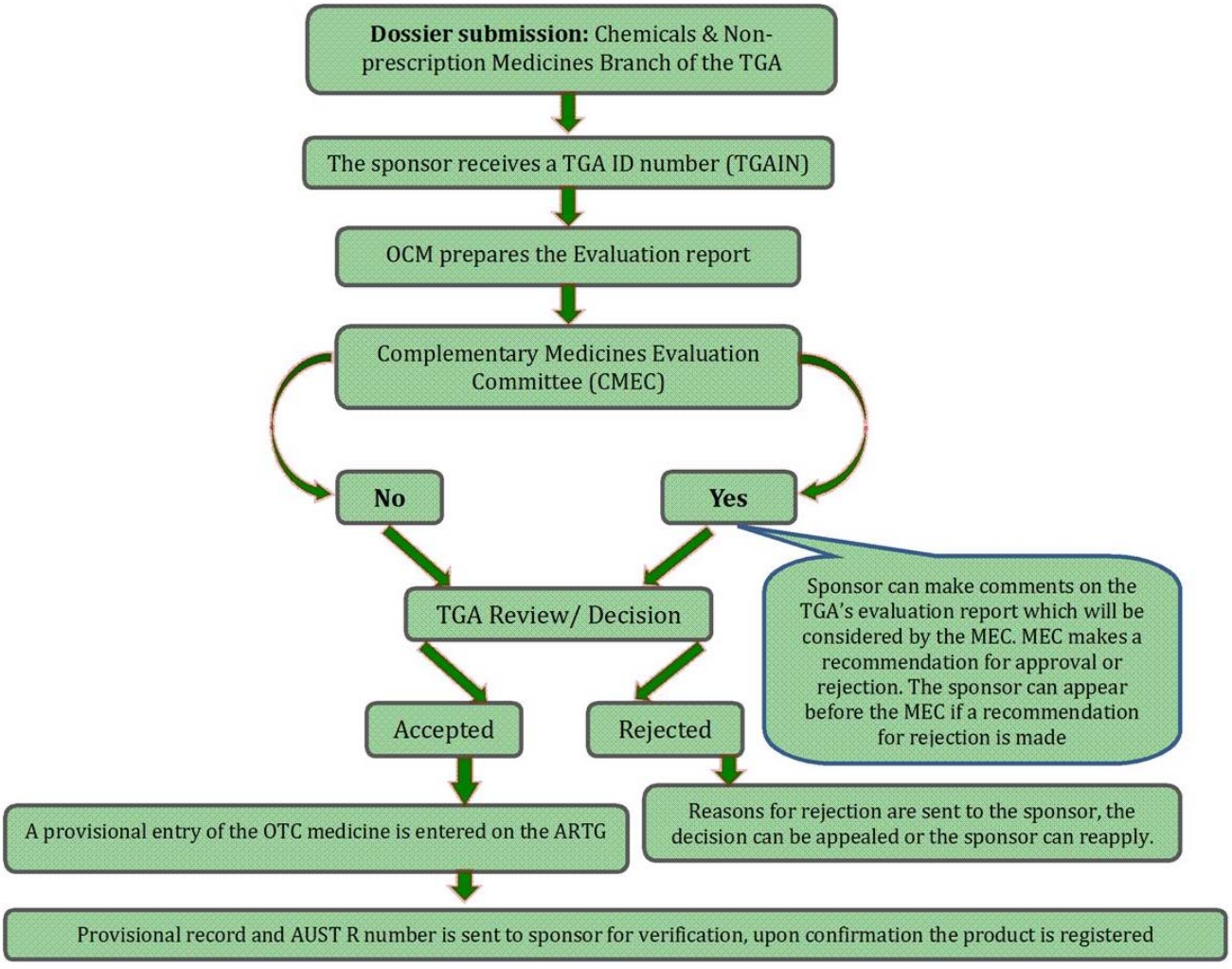

Figure-5: Complementary medicines approval procedure at TGA

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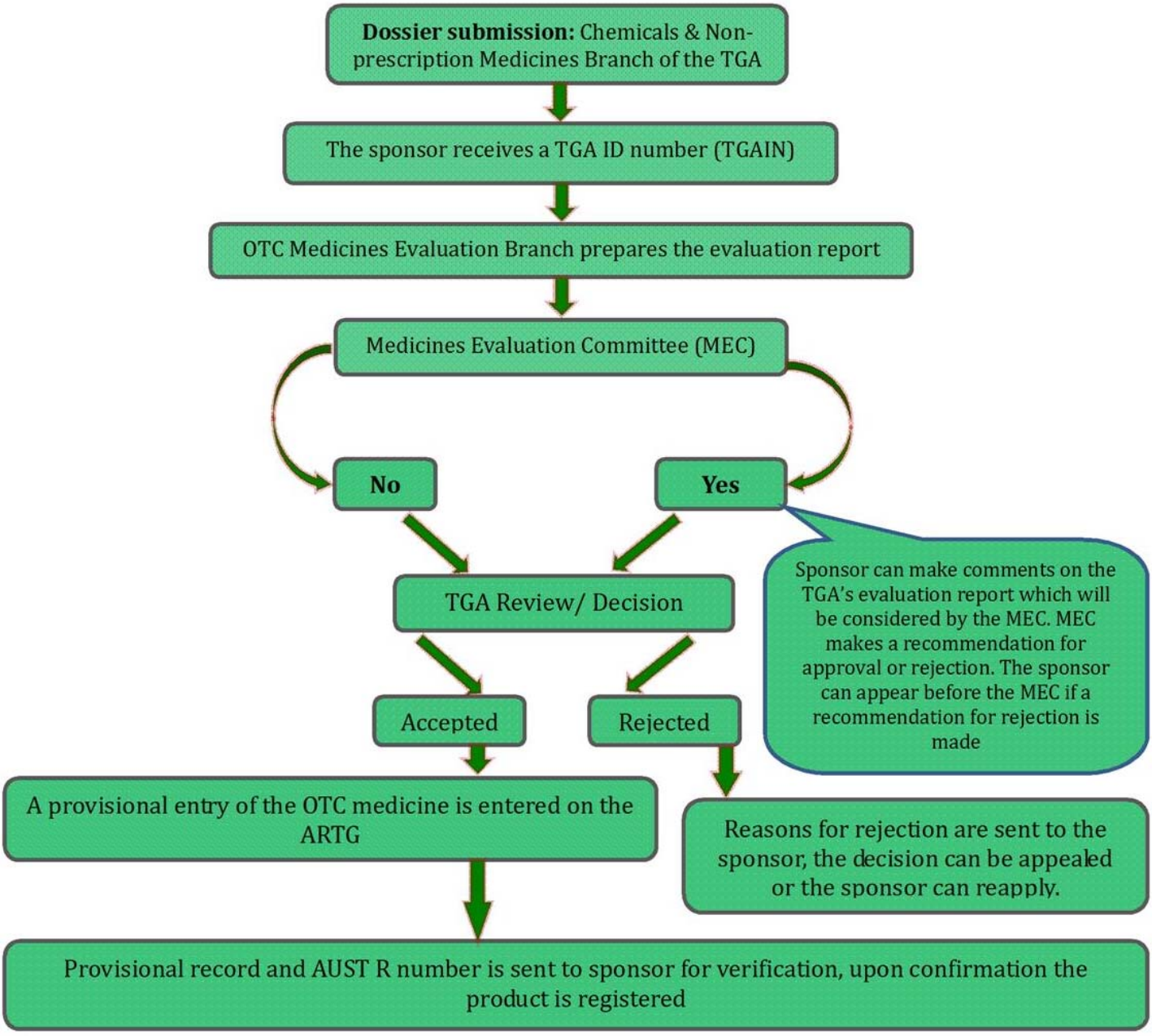

Figure-6: OTC medicines drug approval procedure in Australia

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Complementary Medicines Registration:

Complementary medicines can be registered at ARTG, for registration of complementary medicines the application needs to submit at chemicals and non-prescription medicines branch (CNMB). After paying the application fee TGA will issue the TGA ID number for application. Office of Complementary medicines (OCM) will evaluate the application and prepare the evaluation report. OCM will submit the evaluation report to Complementary Medicines Evaluation Committee (CMEC) for additional evaluation and finally the report sent to TGA. If the report is positive then TGA will give the approval for the product. If the report is negative then applicant can appealed/ reapply to the TGA. Figure-5 represents the flow of complementary medicines approval procedure.

OTC Medicines Registration:

OTC medicines registration procedure also same with the complementary medicines like application submission, TGA ID number issue and evaluation report. OTC application will be evaluated by Medicines Evaluation Committee (MEC). Figure-6 represents the OTC drug approval at TGA

PRESCRIPTION MEDICINES

Prescription medicines are classified in to three categories like, Category-1; Category-2 and Category-3 type applications.

Category 1 applications

- Submission under sub-regulations 16C (3) (b) and 16D (3) (b).
- Category-1 application includes the,
  i. New chemical entities
  ii. New dosage forms,
  iii. New strengths and new generic products
  iv. Extensions of indications and amendments to the Product Information (PI)
  v. Significant variations to an existing application

Category 2 applications

- Submissions under sub-regulations 16C (3)(a) and 16D(3)(a).
- Category 2 application provisions can only be utilized when an application has been previously

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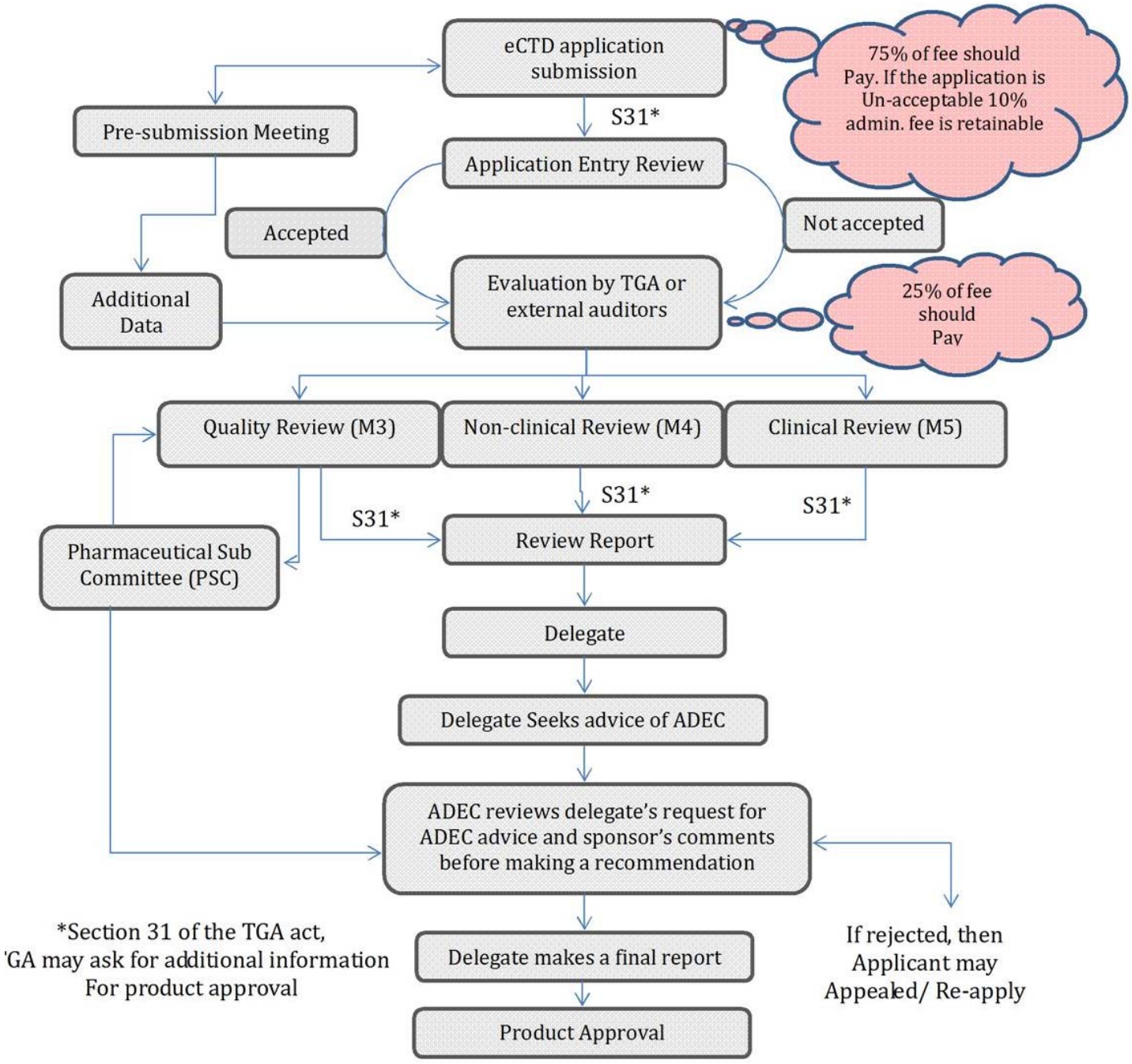

Figure-7: Category-1 and 2 type's application evaluation procedure

approved in two *acceptable countries*. These applications have a shorter statutory time frame for evaluation. Two independent evaluation reports are required from *acceptable countries (Canada, Sweden, The Netherlands, UK and US)*

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- The evaluation reports must be provided as described in sub-regulations 16C (4) and (5) and 16D (4) and (5)). The product should be identical to that registered in the *acceptable countries*, with respect to formulation, directions for use and indications.

Category 3 applications

Category 3 applications are provided for under Regulations 16F and 16G. Category 3 applications involve changes to the quality data of medicines already included on the ARTG, which may or may not render the medicines separate and distinct (and therefore subject to separate registration), and which, in the opinion of the Secretary, do not need to be supported by clinical, non-clinical or bioequivalence data. The types of quality changes subject to a Category 3 application may include, but are not limited to:

- Specifications for the active ingredient, finished product or excipients
- The method of manufacture of the active ingredient and finished product
- The site of manufacture of the active ingredient or the finished product
- The shelf life and storage conditions
- The labeling and packaging, including container type
- A replacement trade name
- Minor changes in formulation.

When submitting a Category 3 application, it may be in the sponsor's interest to provide a justification as to why clinical, non-clinical or bioequivalence data need not be provided.

Sponsors may request a review of the opinion by the Standing Arbitration Committee (SAC) or alternatively, where the opinion relates to the need for bioequivalence data, by the Pharmaceutical Subcommittee (PSC) of the Australian Drug Evaluation Committee (ADEC). If a review is unsuccessful and the sponsor still wishes to pursue the application, two options are available:

- The sponsor may make a new Category 1 or 2 application that includes appropriate clinical, non-clinical or bioequivalence data;

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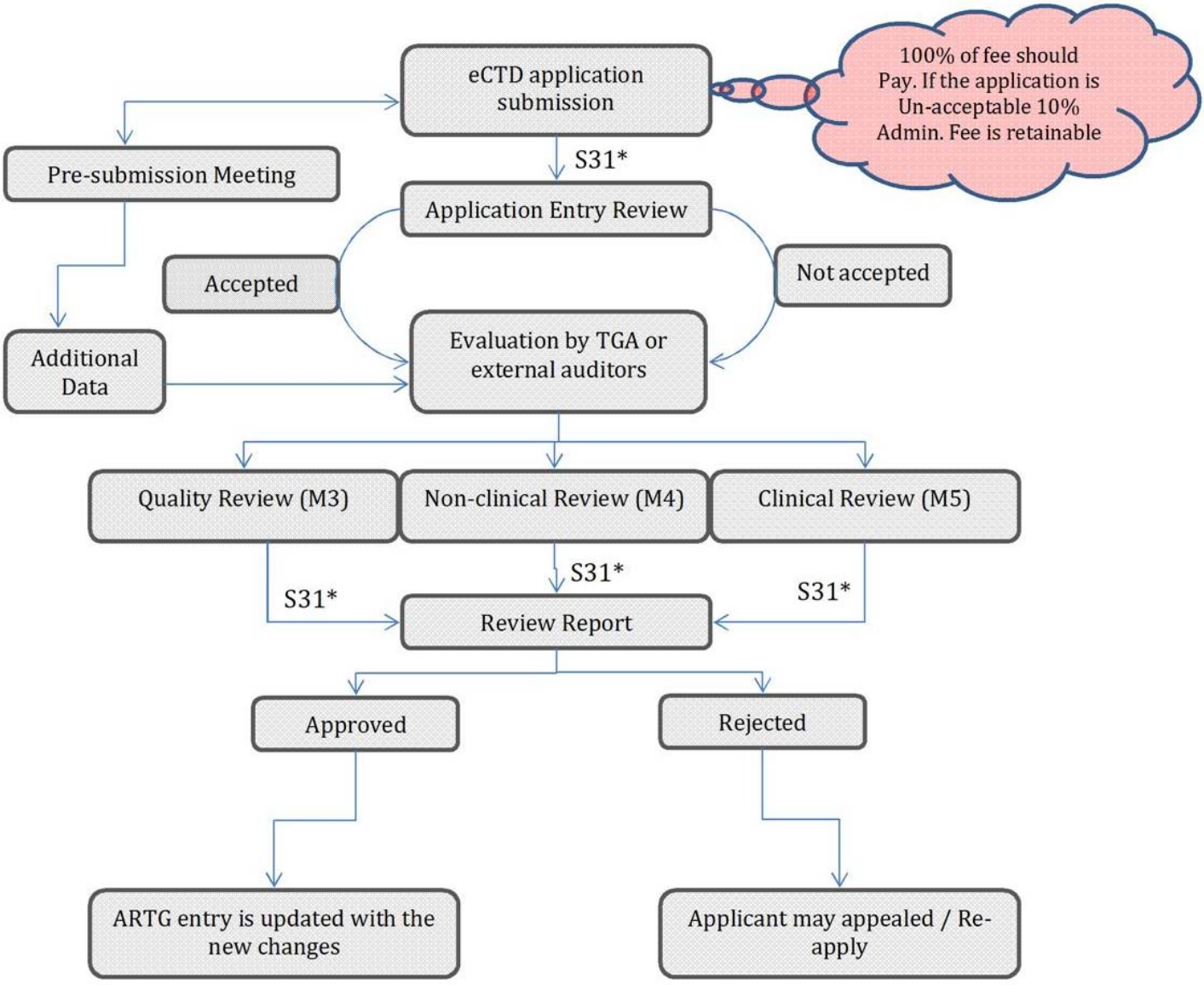

*Section 31 of the TGA act, TGA may ask for additional information for product approval

Figure-8: Category-3 type application evaluation procedure

The new drug evaluation and registration process (ADEC Australian Drug Evaluation Committee stream)

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Pre-submission meetings

A pre-submission meeting is required between TGA Delegates and applicant for certain cases like,

- Complex applications.
- Orphan drug applications.
- Literature based submissions.
- Priority evaluations.
- FDA data package.
- Additional data.
- Fixed Combination Submissions
-

Submission of applications/ Dossier:

Applications should be made using the appropriate *DSEB Application Form*15. Dossier need to prepare as per the eCTD format i.e.

Module 1: *Administrative Information and Prescribing Information For Australia*.
Module-2: Quality Overall Summary
Module-3: Quality
Module-4: Non-clinical data
Module-5: Clinical data

Submission of new data

For administrative purposes, new data submitted by the sponsor, after acceptance of the application for evaluation, are classified in terms of additional data and supplementary data.

- **Additional data are data:** During the evaluation of the application if agency required then the applicant need to provide the additional date for acceptance.
- **Supplementary data:** In the evaluation stage of Clinical or non-clinical data agency will ask the deficiencies to the applicant.

Application acceptance

The Application Entry Team (AET) of the DSEB will conduct an administrative screen of the application before the dossier is accepted for evaluation to ensure that there are no deficiencies that would render the application un-evaluable. If any major deficiencies are found, a request letter for further information will be sent to the applicant. Any deficiencies identified must be addressed with the DSEB before the application can be accepted for evaluation. A screening fee is applicable if the submission is rejected at this point or withdrawn prior to acceptance. If the sponsor has paid insufficient fees, the financial services group (FSG) will raise the invoice for the outstanding amount that must be paid within 2 months. Once the application is accepted for evaluation the applicant will get the letter from TGA, it includes the TGA Identification Number (TGAIN) and a Submission Number. These numbers should be quoted in all subsequent correspondence related to the application.

Evaluation

i. External evaluators

The TGA may contract external evaluators to review aspects of the data. A TGA Delegate will coordinate the evaluation with the external evaluator. The identity of external evaluators is generally kept confidential.

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ii. Section 31 requests

Under Section 31 of the Act, the TGA may request information additional to that provided in the dossier, or may seek clarification of information provided. Such requests are referred to as *Section 31 requests*. For an application, these requests may be issued at any time from submission of the application to marketing approval. The evaluation clock is stopped until a full response to the S31 request is submitted.

All Section 31 (S31) requests are identified with a unique identification number, a *S31 Request Number*. This number should be quoted in the heading of any response to the request.

S31 requests should be answered in full and within the timeframe stipulated in the letter of request. Should a sponsor anticipate difficulty in answering a S31 request in full or within the specified timeframe, they should contact the signatory of the letter to discuss the request as soon after receipt as possible. If a sponsor considers that a S31 request is unreasonable they should discuss this with the Delegate who issued the request. If the sponsor is not satisfied with the outcome of the discussion, the sponsor may request a review of the issue by the Standing Arbitration Committee (SAC) or Pharmaceutical Sub-Committee (PSC)

Section 31 requests regarding a closed part of a Drug Master File (DMF) or Plasma Master File (PMF) will be sent by TGA directly to the manufacturer concerned. The TGA will notify the sponsor that this request has been made.

Processing times

- The time taken for the sponsor to respond to Section 31 requests is excluded from the processing times.
- The time allowed for evaluation of the application will be extended by the time taken to respond fully to the request.
- Partial responses to a Section 31 request will not restart the evaluation clock. Also, should a response not contain the S31 Request Number, the evaluation clock will not restart until 5 working days after receipt of the sponsor's response to allow for matching the response with the original request.

Category 1 and 2 applications

For Category 1 and 2 applications, the processing time comprises a period for acceptance of the application and a period for evaluation, which begins on the day that the TGA notifies acceptance of the application.

Application status	Required working days
Category 1 applications	
Application submission to acceptance for evaluation	40
Evaluation time	255
Category 2 applications	
Application submission to acceptance for evaluation	20
Evaluation time	175
Application status	**Fee value**
Category 1 and 2 applications	
Application submission	75% of fee value
Evaluation time	25% of fee value

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Where the TGA does not complete the processing of a Category 1 or 2 applications within the statutory evaluation time, the remaining 25% of the evaluation fee is not payable. However, the evaluation will still proceed to a decision by the Secretary and the sponsor may not market the product until registration is approved. If an evaluation has not been completed within time the sponsor may notify the Secretary in writing that the sponsor wishes to treat the application as having been refused. The sponsor may then proceed with a request for reconsideration. The TGA targets the following mean evaluation times, excluding any clock stops to respond to S31 questions, for different types of application:

- ✓ New chemical entities, 150 working days
- ✓ New generics, other than additional trade names only, 100 working days
- ✓ New indications, 160 working days
- ✓ Product Information changes, 90 working days
- ✓ Additional trade names only, 45 working days (see Section 4.3.1 for exceptions)
- ✓ Other Category 1 applications, 130 working days.

Priority evaluations

Formal timeframes have not been established for priority evaluations. It is expected that priority evaluations will be completed as quickly as possible and within the above target timeframes. However, this is dependent upon the receipt of a complete submission and prompt responses to any questions raised.

Category 3 applications

- ➢ For Category 3 applications, there is a single processing period, which begins on the day of lodgement of the application (within 45 working days of receipt of the application) or payment of the evaluation fee, whichever is the later day.
- ➢ If, under the provisions of sub regulation 16F(3)(b), the Secretary raises an objection to the application, the applicant may respond and provide further information or data.
- ➢ A further 30 working days from receipt of this response is then allowed for consideration of the response before the application must be approved or rejected.

Approved medicines status:

TGA will provide the searching data base for the registered/ listed medicines through ARTG data base. We have a facility for searching the active ingredient, product type and sponsor options (https://www.ebs.tga.gov.au/).

CONCLUSION

TGA is monitoring the all aspects for drug approvals and monitoring the human health. As per the TGA act all the medicines are classified in to prescription, non-prescription medicines and export only medicines. Prescription medicines are classified in to three categories like, Category-1; Category-2 and Category-3 type applications. TGA act states those medicines require registering or listing at TGA. Registration and listing requirements are based on the level of risk. All prescription and some non-prescription medicines are required to register at TGA and some non-prescription medicines and export only medicines are need to list at TGA. TGA has adopted the most of the EDQM guidelines for medicines. TGA has also increased the generic products approvals for supporting the patients with fewer prices. Post marketing activities of the TGA include investigating reports of problems, laboratory testing of products on the market, and monitoring to ensure compliance with the legislation.

DISCLIMER

This review is only for the educational purpose only and data collected from the official websites.

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