



亞法貝德生技電子報

公 司 新 聞

- ◆ 財團法人醫藥工業技術發展中心將於 108 年 8 月 5 日辦理 2019 醫療器材產品法規與臨床實務 (高雄場)訓練課程，亞法貝德生技張琬琦執行長將應邀分享「醫療器材臨床試驗之統計方法」議題，歡迎有興趣者可以就近與會，詳細課程之日期地點與議程資訊、報名方式等，請參閱報名資訊：

https://www.mdic.org.tw/Train_detail/1281

- ◆ 亞法貝德生技籌備今年 5 月竹北場「歐美醫材法規與臨床驗證策略」研討會時，已有許多學員陸續表示未來期望能有台北場次以便就近聆聽。亞法貝德生技首先感謝竹北場學員熱烈參與，針對該場次學員書面意見回饋最想參與課題，特別舉辦 108 年 10 月 4 日台北場「醫材臨床試驗送審規劃與收案管理」介紹醫療器材臨床試驗送審規劃，並分享歐盟臨床評估報告撰寫技巧，本場次也讓學員體驗試驗送審可能遭遇到之實境，輔助本公司獨創設計之桌遊分組互動，演練收案團隊管理決策，並搭配醫材個案作臨床文獻導讀與試驗解析，歡迎各界踴躍報名本次活動！

報名網址：<https://ppt.cc/fj7Wfx>

~~~~~議程請詳見下頁~~~~~

亞法貝德生技歡迎各界投稿與諮詢指教！ [alfabetacro.com](http://alfabetacro.com)



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研討會名稱：醫材臨床試驗送審規劃與收案管理

時間：2019 年 10 月 04 日(上午 9:00~16:30)

地點：雙連教會 9 樓聯誼廳 (台北市中山北路二段 111 號 9 樓)

### 2019.10.04 議程表

| 時間            | 主題與講者                                   |
|---------------|-----------------------------------------|
| 09:00 - 09:30 | 報到                                      |
| 09:30 - 10:30 | 醫材類似品檢索策略與試驗設計<br>亞法貝德生技執行長/張琬琦 博士      |
| 10:30 - 10:50 | 茶敘                                      |
| 10:50 - 12:00 | 歐盟臨床評估報告撰寫介紹<br>亞法貝德生技執行長/張琬琦 博士        |
| 12:00 - 13:00 | 午餐與休憩                                   |
| 13:00 - 14:30 | 醫材試驗送審與收案團隊管理—分組演練<br>亞法貝德生技專案經理/黃馨 博士  |
| 14:30 - 14:50 | 茶敘                                      |
| 14:50 - 16:20 | 醫材臨床文獻導讀與試驗解析—個案討論<br>亞法貝德生技副總經理/王琬斯 博士 |
| 16:20         | 會後交流與賦歸                                 |

報名網址：<https://ppt.cc/fj7Wfx>

匯款銀行：台灣銀行六家分行 004      帳號：248001027016

戶名：亞法貝德生技股份有限公司

費用：8/31 前報名繳費享早鳥價 2500 元，9/1~9/30 恢復原價 3000 元



## 澳洲 TGA 醫藥品產品分級檢索

澳洲主管醫療器材管制的機關為診療產品局 (Therapeutic Goods Administration, TGA)。其醫療器材分級方式與歐盟非常相似，分為 Class I、II、III、AIMD 及 IVD 等級。Class I：為低風險的產品，包括非侵入式，簡易或短暫使用的器材例如聽診器、醫檢手套、假牙、敷料及簡單的外科器械等。Class II：中度風險，如同歐盟的醫療器材指令，又進一步分為 Class II a, Class II b 兩級。Class II a 是非侵入式器材、特殊敷料、短暫侵入式器材、主動式診斷器材、一般醫院用的設備、家用的消毒器材等。Class II b 包括有癒合功效的敷料、侵入式外科器械、植入式器材、主動式器材、避孕器材及血袋等。Class III：高度風險，包括以手術方式侵入的器材、心導管可吸收式縫線、人工心瓣膜與膠原蛋白製成的植入物等。AIMD：主動植入式醫療器材，同 Class III 器材管制。IVD：體外診斷醫療器材。

根據 1989 年的診療產品法(Therapeutic Goods Act 1989)，進口或在澳洲國內製造銷售的醫療器材都必須接受 TGA 的管制。目前澳洲的醫療器材上市前管制是採用 Australian Register of Therapeutic Goods (ARTG) 的查驗登記制度，除了經過 TGA 公告免除者以外，輸入或澳洲國產的醫療器材都必須申請登記。澳洲是全球調和化小組 (Global Harmonization Task Force, GHTF) 的創始成員之一，於 1998 年與歐盟簽署醫療器材相互認可協定，因此國會審議中的新醫療器材法規將與國際調和，特別是與歐盟的醫療器材指令相符，唯一的差別是，澳洲將不會採用認可民營的第三者機構（如歐盟的指定機構 Notified Body) 的方式，醫療器材的上市前審查與品質系統查核均由 TGA 執行。



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下列步驟介紹 TGA 資料庫搜尋醫材產品：

## 1. TGA ARTG 網址：

<https://www.tga.gov.au/medicines-and-tga-classifications>

Department of Health  
Therapeutic Goods Administration

Search TG

Home Safety information Consumers Health professionals Industry About the TGA News room

Industry

Home » Industry » Regulation basics » How therapeutic goods are regulated in Australia

**Medicines and TGA classifications**

Australia has a two-tiered system for the regulation of medicines, including complementary medicines:

- Higher risk medicines must be registered on the Australian Register of Therapeutic Goods (ARTG), which involves individually evaluating the quality, safety and effectiveness of the product.
- Lower risk medicines containing pre-approved, low-risk ingredients and that make limited claims can be listed on the ARTG.

Within the regulatory framework, medicines are classified as either registered or listed:

**Registered medicines**

Registered medicines are assessed by the TGA for quality, safety and efficacy.

## 2. 點選藍色標示 Search the ARTG

SME Assist

Regulation basics

How therapeutic goods are regulated in Australia

Australian Register of Therapeutic Goods

Industry educational materials

Legislation & legislative instruments

Advertising hub

Labelling & packaging

Import and export

Clinical trials

Cosmetics

Scientific guidelines

Therapeutic goods entered in the Australian Register of Therapeutic Goods (ARTG) can be lawfully supplied in Australia.

**Information held in the ARTG**

Information held in the ARTG includes:

- product name and formulation details
- sponsor (company) and manufacturer details

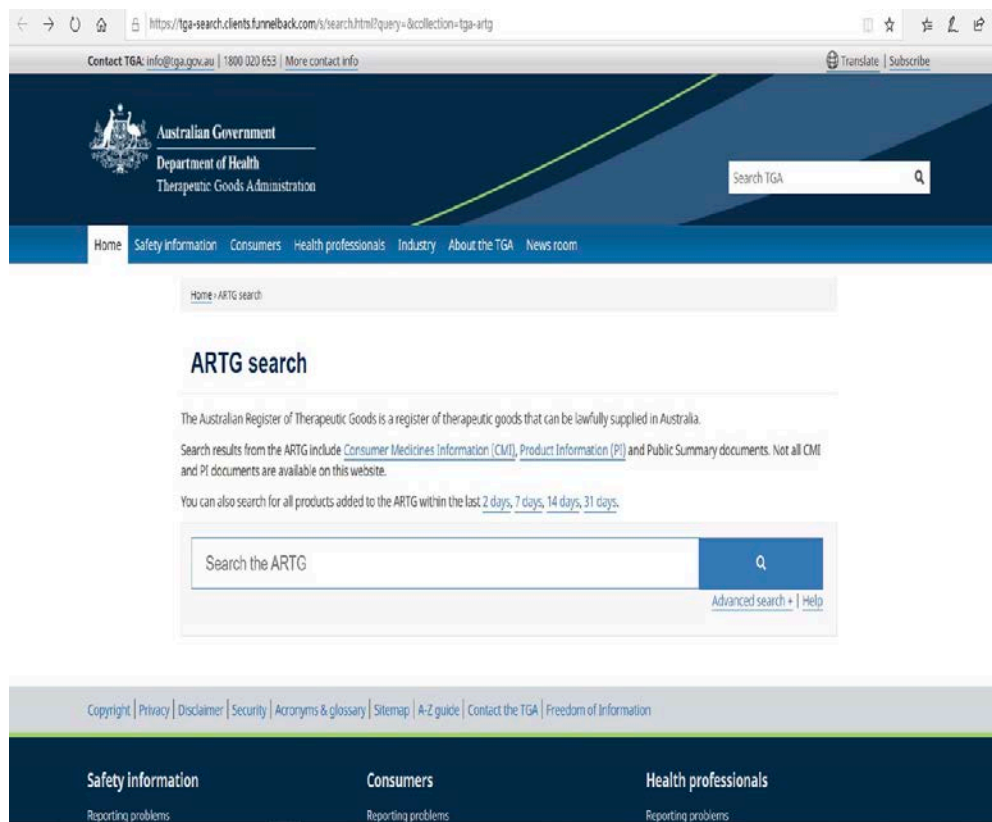
**View public, sponsor or manufacturer information on the ARTG**

There were approximately 86,896 products on the Australian Register of Therapeutic Goods as at April 2016.

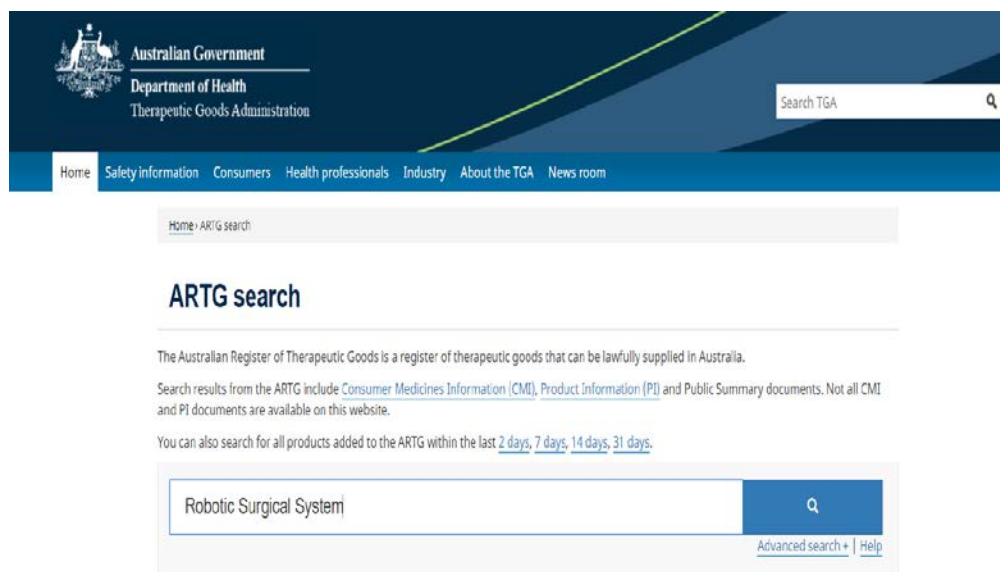
**Search the ARTG**



### 3. ARTG 檢索介面



### 4. 鍵入關鍵字搜尋 (關鍵字:Robotic Surgical System)





## 5. 鍵入關鍵字搜尋 (關鍵字:Robotic Surgical System), 出現檢索結果

### ARTG search

The Australian Register of Therapeutic Goods is a register of therapeutic goods that can be lawfully supplied in Australia.

Search results from the ARTG include [Consumer Medicines Information \(CMI\)](#), [Product Information \(PI\)](#) and Public Summary documents. Not all CMI and PI documents are available on this website.

You can also search for all products added to the ARTG within the last [2 days](#), [7 days](#), [14 days](#), [31 days](#).

Robotic Surgical System



[Advanced search +](#) | [Help](#)

### ARTG, PI and CMI results

[ Query: Robotic Surgical System -- Documents: 18 fully matching plus 480 partially matching ]

#### 1. [Brainlab Australia Pty Ltd - Surgical Navigation Planning Software -...](#)

- **ARTG ID:** 319846
- **Product name:** Surgical Navigation Planning Software - Robotic surgical system software, navigation
- **Sponsor:** Brainlab Australia Pty Ltd
- **Manufacturer:** BrainLAB AG

#### 2. [Zimmer Biomet Pty Ltd - ROSA® KNEE SYSTEM - Robotic surgical system](#)

- **ARTG ID:** 313971
- **Product name:** ROSA® KNEE SYSTEM - Robotic surgical system
- **Sponsor:** Zimmer Biomet Pty Ltd
- **Manufacturer:** Zimmer CAS

#### 3. [Mathys Orthopaedics Pty Ltd - Robotic surgical system](#)

- **ARTG ID:** 298989
- **Product name:** Robotic surgical system
- **Sponsor:** Mathys Orthopaedics Pty Ltd

## 6. 點選任一產品，畫面如下:

← → 🔍 🏠

Department of Health  
Therapeutic Goods Administration

Search TGA

Home Safety information Consumers Health professionals Industry About the TGA News room

Home > ARTG search

### ARTG search

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Search the ARTG

[Advanced search +](#) | [Help](#)

### ARTG ID 232447

|                     |                                                                            |
|---------------------|----------------------------------------------------------------------------|
| Product name        | Meileuca Recover AI                                                        |
| Active ingredients  | curcumin, Camellia sinensis, Harpagophytum procumbens, Zingiber officinale |
| Sponsor name        | Meileuca of Australia and New Zealand Pty Ltd                              |
| ARTG entry for      | Medicine Listed                                                            |
| Public ARTG summary | <a href="#">ARTG ID 232447 - public ARTG summary [pdf]</a>                 |





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7. 點選 Public ARTG summary, 顯示 PDF 第一頁畫面如下(第二頁省略):

  
**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 232447 Melaleuca Recover AI

**ARTG entry for** Medicine Listed

**Sponsor** Melaleuca of Australia and New Zealand Pty Ltd

**Postal Address** PO BOX 733, Balwyn, VIC, 3103  
Australia

**ARTG Start Date** 8/01/2015

**Product category** Medicine

**Status** Active

**Approval area** Listed Medicines

**Conditions**

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

**Products**

**1. Melaleuca Recover AI**

| Product Type                          | Single Medicine Product                                                                                                                                                                                                                 | Effective date | 8/01/2015 |
|---------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|-----------|
| <b>Permitted Indications</b>          | No Permitted Indications included on Record                                                                                                                                                                                             |                |           |
| <b>Indication Requirements</b>        | No Indication Requirements included on Record                                                                                                                                                                                           |                |           |
| <b>Standard Indications</b>           | May temporarily relieve joint pain/aches associated with mild arthritis<br>May relieve mild rheumatic joint pain                                                                                                                        |                |           |
| <b>Specific Indications</b>           | Muscle and joint anti-inflammatory.<br>Helps relieve mild joint pain and stiffness as well as helping to decrease muscle aches and pains.<br>Helps decrease/reduce/relieve mild joint and muscular aches, swelling, pain and stiffness. |                |           |
| <b>Warnings</b>                       | If symptoms persist consult your healthcare practitioner (or words to that effect).                                                                                                                                                     |                |           |
| <b>Additional Product information</b> |                                                                                                                                                                                                                                         |                |           |
| <b>Pack Size/Poison information</b>   |                                                                                                                                                                                                                                         |                |           |
| <b>Pack Size</b>                      |                                                                                                                                                                                                                                         |                |           |
| <b>Components</b>                     |                                                                                                                                                                                                                                         |                |           |
| <b>1. Formulation 1</b>               |                                                                                                                                                                                                                                         |                |           |
| <b>Poison Schedule</b>                |                                                                                                                                                                                                                                         |                |           |

Page 1 of 2  
This is not an ARTG Certificate document.  
The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.  
Visit [www.tga.gov.au](http://www.tga.gov.au) for contact information

Produced at 16.07.2019 at 05:28:21 AEST

Public Summary

TGA ARTG 的資料庫很適合作歐盟分級參考, 若您對歐澳醫材產品分級有其他疑問, 歡迎洽詢亞法貝德生技, 我們將為您服務。



## 淺談醫療器材管理法草案

新的醫療器材管理法催生為近期在台灣醫材法規重要的新聞之一。現階段台灣醫療器材管理規範仍是基於藥事法，而該法中的「藥物」則包括藥品及醫療器材，但醫療器材的管理乃基於產品風險程度作分類分級控管，與藥品的管理不同，再加上近年來醫療器材產業蓬勃發展，醫材商經營模式也與藥品有所差異，衛生福利部於民國 105 年 11 月 5 日公布了醫療器材管理法草案，擬將醫療器材獨立於藥事法外另以專法規範，以便與國際接軌。此項草案已於民國 106 年 12 月 14 日經行政院會通過，目前正於立法院朝野黨團協商階段。

醫療器材管理法分為九個章節共 84 條，包括了第一章總則、第二章製造販賣之管理、第三章醫療器材之登錄與查驗登記、第四章醫療器材臨床試驗之管理、第五章醫療器材廣告之管理、第六章監督及預防、第七章稽查與取締、第八章罰則與第九章附則等。以下列出本法重大變革要點：

- ◆ 第十條:醫療器材製造業者除了從事醫療器材製造、包裝、貼標、滅菌或最終驗放，另外也納入從事醫材設計並以其名義於市場流通者作醫療器材製造業者管理。
- ◆ 第十一條: 將從事租賃或維修業務者納入販賣業者作管理。衛福部希望藉由這兩項條文提高學術界研發高階醫材產品之意願和健全醫療器材產業管理。
- ◆ 第二十四條:為了確保醫療器材出廠後之品質，不會因為儲存運輸或配送等過長而減損並增加風險，以保障民眾健康。經中央主管機關公告之醫療器材與醫療器材商應建立優良運銷系統，並經檢查合格取得許可後，始得從事批發輸入或輸出。這項規則也意味著未來醫療器材的運送業者必須遵循





## 淺談醫療器材管理法草案（續）

特別的規範，對運輸業也是一項新的挑戰。

- ◆ 第二十五條: 明示醫療器材的登錄與查驗登記制度之重大改變，為了簡化上市前的審查程序，針對部分低風險的醫療器材可免查驗而改用廠商直接上網登錄制度，但主管機關會加強登錄資料查核以及上市後的複查和稽查以確保產品資料真實性和品質。
- ◆ 第二十八條: 採登錄制度之醫療器材商須向中央主管機關每年定期辦理年度申報，已延續登錄效力。
- ◆ 第三十七條第一項: 為確保受試者安全，明定規範執行臨床試驗應報請中央主管機關核准，惟依產品使用及預期不良反應之可能產生之風險，經考量評估其無顯著風險者，無須申請，以簡化管理。
- ◆ 第四十五條: 放寬了醫材廣告登載的限制，未來醫療器材為專供醫事人員使用或經公告指定者，不限刊載於藥事法規定之學術性醫療刊物，亦得廣告於專供醫事人員使用之醫療刊物、傳播媒體及醫療學術性相關活動。

正如醫療器材管理法草案一開始所闡明，為了健全醫療器材管理週期和民眾健康，以及跟上世界其他先進國家的醫材管理辦法，醫療器材專法似乎勢在必行，未來就只等著本期立法院朝野審查進度了。