



**Australian Government**  

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**Department of Health and Ageing**  
**Therapeutic Goods Administration**



# **Proposed Australia New Zealand Therapeutic Products Authority (ANZTPA)**

## **Product Licence**

**September 2006**

# PROPOSED AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AUTHORITY (ANZTPA) PRODUCT LICENCE

## BACKGROUND:

The Australia New Zealand Therapeutic Products Authority (the Authority) register is to be developed to hold information for medicines, medical devices, blood products, human tissue and other therapeutic products marketed in Australia and New Zealand. On day one of the Authority, the system will be required to issue an interim product licence to enable continued supply, manufacture, import or export of products under the conditions of their existing approval in Australia or New Zealand respectively.

The product licence document must comply with the following requirements:

- The product licence document will provide a summary of the particulars of the medicine(s)/medical device(s) etc that is/are the subject of the licence, and set out or refer to the conditions, subject to which the licence has been granted. The product licence will include:
  - *the product licence identifier;*
  - *the date the product licence was granted;*
  - *the dates and details of variations to the licence;*
  - *the country(ies) in which the product licence is valid;*
  - *particulars about:*
    - *the licence holder;*
    - *the medicine(s) or medical device(s);*
    - *the manufacture of the medicine(s) or medical device(s), including manufacturers; and*
    - *the intended use of the medicine(s) or intended purpose of the medical device(s); (this is taken to be the product indication)*
  - *the conditions subject to which the product licence is granted; and*
  - *other information relevant to the issuing of the licence.*
- The particulars included on the product licence may vary depending on the classification of the medicine or medical device.
- Generally, a product licence will remain valid provided annual fees are paid and the product licence is not suspended or revoked. The exception will be the provisional product licence, which will be issued for a time-limited period.

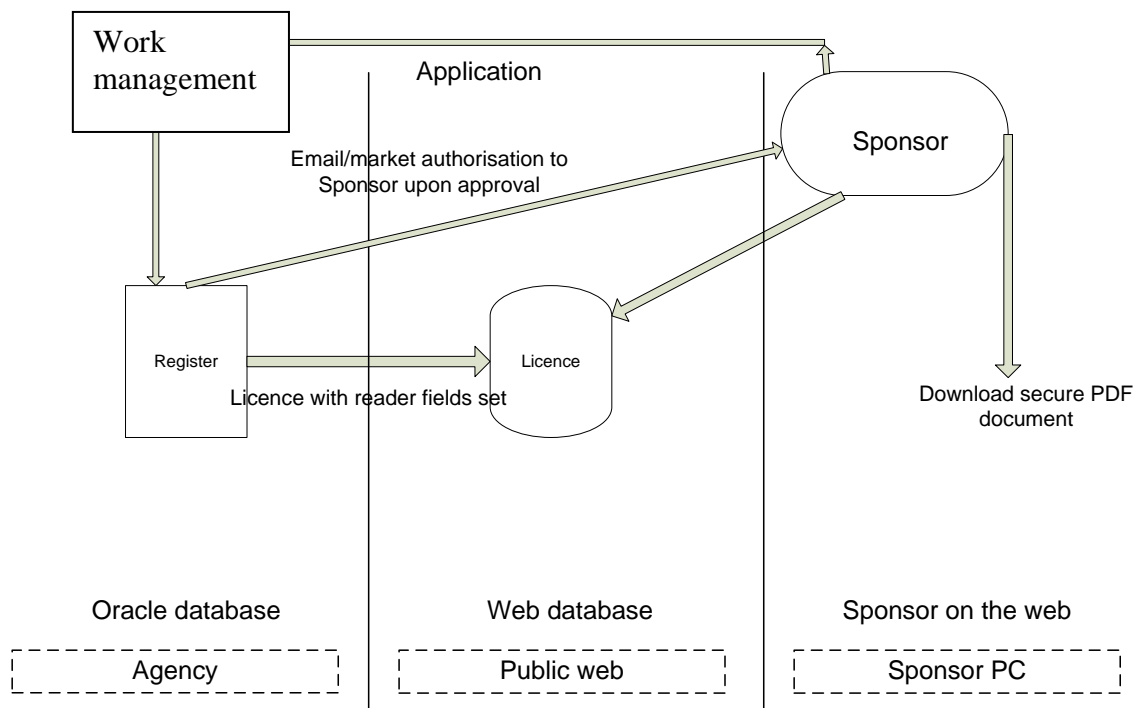
## The Product Licence

The product licence is a document issued by the Authority to the licence holder of the product. The licence document will be an “extract” of information contained in the Authority register.

However, licence holders will have electronic access to their complete register details through the Authority “On Line Service” functionality. Information that will be reported in the licence document will be held in a new “licence document” table in the Authority register and changes to the information will be managed through strict version control.

The licence document table will hold the agreed extract of information and will be populated upon any change to the register information, regardless of whether the information that is changed appears on the licence or not. The update function is required to meet the legislative requirement to record “variation reasons” on the licence. The versioning of the licence table will provide the necessary legal confidence to assure traceability of the details on the licence document.

The licence document will be created upon change to the register record and pushed to a Lotus Notes licence database on the web where licence holders will be able to download a copy of the product licence, where access will be based on the standard web access security model.



**Owner notification**

The address to enable notification of the availability of a licence will be provided from the Client database which will be amended to include a company (Client) regulatory contact email address and provide functionality to enable its management by the Client.

Client will carry several “email” addresses for future Authority electronic communication. These will include an invoicing address to support Great Plains and the licence address. The contact details will be used to send an email or market authorisation to the Client upon approval of a new application or upon variation to existing product details.

The content of the email could contain a return link to the product licence database which will be accessed by User Id and password.

### **Day One of the Authority**

An electronic licence document (the interim product licence) will be created for all current (active) products recorded on the Authority register. The licence table will be populated with agreed licence information and replicated to the Lotus Notes licence database to be created as part of the Authority On Line Service environment. Access will be governed by the same rules that allow access to the ARTG Sponsor web – product licences can be seen and downloaded by a licence holder and/or their appointed Agent. The licence holder or Agent will be able to download a copy of the interim product licence from the database rather than the Authority directly emailing a copy. The same database could be used to provide “public access” to licence information and a different licence report configured for their perusal. The “information set” would probably exclude manufacturer information.

### **After day one**

Any addition of or variation to a record on the Authority register will result in the creation of a “new version” of the licence which will then be “published” to the web Licence database for access by its owner. At a minimum, the push to the web would align with the current practise of updating information each night.

The electronic process will have to address the specific requirement to cover product transfer functionality (where ownership of the licence is changed). The Authority record could show ownership was transferred “today” however this would not be reflected on the web till the next day. A licence downloaded “today” would misrepresent information held by the Authority.

In the event of a licence variation, the current business practise of updating web information nightly will probably have to be amended, particularly where the product has been the subject of a transfer of ownership. The web Notes database would ideally be updated within the hour of a licence version change, similar to updating the corporate code tables.

### **The product licence:**

The Product Licence is what authorises the licence holder to supply the product in Australia and / or New Zealand. The information on the product licence will be drawn from the set of information held on the Authority register. The product licence will define a set of agreed product characteristics that clearly and uniquely identify the product that is licensed. These characteristics will vary subject to the registration type (medicine, medical device, or biological) and risk classification of the product.

The Authority register will not contain all information to which supply of the product will be expected to conform. The new model does however contain the capability to record placeholders for information sources used in the product approval and its ongoing “management”. Internal administrative fields are only shown to Authority staff.

While contraindications for use, dosing instructions etc are not included on the register an option to provide links to external web or reference sites is contained in the design.

The Authority register will carry a record of information change based on broad information grouping criteria. Each field variation will be recorded in relevant audit trails, while the high level variation record will provide a visible accountability for the record integrity. All changes or variations will result in a value change rather than carry a reference to a filed decision.

The following variables will make up the product licence:

**(A) Licence type**

Provisional, Interim, Export Only, Export (or permutations of each)

The licence will not carry a qualifier for a full licence as the default is an “Authority Licence”.

**(B) Licence holder name**

Name of the licence holder

**(C) Licence product name (list if relevant)**

The licence will list all products covered by the licence. The purpose is to clearly identify the product(s) authorised for supply under the licence. Each product will comply with the medicine/ medical devices rules for separate and distinct.

**(D) Country name on licence**

Where the licence status is interim, the licence will show the country for supply, whereas an Authority licence will not show the country as the default is assumed to allow supply into both countries. A single country licence as approved under Article 11 will not carry the country name – the licence is approved as an Authority licence and the status of single country only supply will be recorded as a standard condition on the licence.

**(E) Authority Licence identifier      M-2-0000001**

The first character will define the licence therapeutic type, M medicine, D medical device, B biological or T Other Therapeutic Product.

The second character will define the class of the product (For medicines – 1 or 2. For medical devices - 1, Im, 1s, IIa, IIb, III, AIMD).

The third string is a unique incrementing number issued by the register.

The Class of a medicine or medical device migrated from the ARTG will translate based on the current Class, Registered, or Listed categorisation. Class a direct migration, Registered to Class 2, Listed to Class 1.

The incrementing number that is assigned to the interim licence will not change as part of the transition to an Authority licence. The number will be permanently associated with the product.

**(F) Date Authority licence issued**

If the licence status is “provisional”, the date approved-to will also be displayed.

**(G) Product category**

The product category will be populated from the licence product category field. Complementary medicine, Prescription medicine, OTC medicine, Medical device, IVD, OTG, Blood, Blood component, Human tissue, Human cell or Other Therapeutic Product.

The type descriptor will be preceded by the product Class.

**(H) Manufacturer details**

Manufacturer name, State/Region and County, Steps of manufacture.

Please note, most SMARTI records do not include steps of manufacture. This information will be missing on interim licences for New Zealand.

**(I) Licence Standard conditions**

Licence Standard conditions are imposed as defaults under the legislation. They are recorded at the licence level. Standard conditions will reference the legislation rather than be included on the licence as individual conditions as is currently the practice on an ARTG certificate.

Eg. For Class 1 medicine: “The medicine is licensed subject to those conditions as specified in Division 3.7 section 3.42 of the Medicine Rule.”

**(J) Licence Variations**

List of changes to a licence and when they occurred. The changes will be recorded at the licence level, not the product level. The variation reasons will be based on a code table to reflect areas of change in the entry rather than specific field items and include the date of change. The changes cannot create a separate and distinct product.

**(K) List of products covered by the licence**

Only current product names will be shown.

**(L) Product shelf life information**

Product shelf life information will be displayed for Class 2 medicines.

**(M) Product Specific Conditions** (words that are provided as part of the approval process)

Product Specific conditions are imposed at the product level and will be included on the licence per product.

**(N) Product Indications**

The Product Licence will show standard (based on a code lookup as for listed medicines) and specific indications (as imposed by DSEB etc) at the product level. This is a departure from the current ARTG model and allows the regulator to establish a direct relationship between a product and its indications. Where a new indication is approved, the register record will “inactivate” the current product and create a new product record.

**(O) Product Warnings**

All warnings, both coded and free text are to be shown.

**(P) Formulation**

The new grouping rules for the Authority allow many concurrent products under one licence, where the products may contain different quantities of “restricted” ingredients. Accordingly the licence should contain sufficient formulation detail to show the similarity or otherwise of a product.

The licence should list the active ingredients with quantities, while the detail of excipient information will be displayed subject to the level of information recorded on the register.

Excipient name and quantity information for a Class 2 medicine is recorded on the register. Excipient detail for a Class 1 medicine however is determined by lodgement rules, for example provide quantities for restricted excipient ingredients. Applicants however can elect to record additional excipient formulation detail. Accordingly excipient information for a Class 1 will show the information as recorded on the register. No filter rules will be applied.

**ANZTPA**

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**EXAMPLE  
ONLY**

**Authority (A) Product Licence**

Issued to

**(B) XXX of Australia Limited  
for approval to supply**

**(C) XXX Strong Pain Plus**

In

**(D) (If Interim) Australia or New Zealand  
(If Authority) not on licence as both is default**

**(E) Authority Product Licence Identifier** M-2-000001 (M for medicine, 2 for Class, and incrementing number. The M is the licence\_therapeutic\_type)

**(F) Date Authority Licence issued** 30 Nov 2004

**(G) Product type** Class 2 OTC Medicine

**(H) Manufacturer(s)**

XXX Healthcare	TEXAS, United States of America	Manufacturer of Proprietary Ingredient
XXX Pharmaceuticals Pty Ltd	SMITHTOWN, Australia	Finished product manufacture; Packaging and labelling; Quality Control; Release for supply; Testing Laboratory
XXX Pack Sealers Pty Ltd	SMITHVILLE, Australia	Packaging
XXX Pharmaceuticals Pty Ltd	SMITH CITY, Australia	Testing Laboratory
XXX Pharmaceuticals Pty Ltd	SMITHVILLE SOUTH, Australia	Finished product manufacture; Quality Control; Packaging; Testing Laboratory; Release for supply
XXX Technologies Pty Ltd	SMITHWOOD, Australia	Packaging
XXX Packaging Pty Ltd	SMITHWEST, Australia	Packaging
XXX Industries Pty Ltd	SMITH CREEK, Australia	Packaging
XXX Pharmaceuticals Pty Ltd	SMITHTOWN, Australia	Finished product manufacture; Quality Control; Packaging; Testing Laboratory; Labelling; Release for supply

This product licence has been issued subject to the following conditions:

**(I) This licence is issued subject to the following conditions:**

- (i) Conditions applicable to all Product Licences** specified in Division 3.7 section 3.42 of the Medicine Rule.
- (ii) Additional conditions- Class 2 medicine as** specified in Division 3.7 section 3.44 of the Medicine Rule.
- (ii) Discretionary Conditions as permitted under Division 3.7 section 3.46 of the Medicines Rule**  
-actual conditions to be specified in the licence document

Note: there will need to be a different version for medical devices specifying the relevant sections in the Medical Devices Rule.

**(J) Licence Variations**

<u>Change reason</u>	<u>Date</u>
Formulation changes - excipient ingredients	2/3/2004
Label changes (including package insert)	5/9/2004
Product detail changes	17/12/2004

**(K) Products covered by the licence**

194528 XXX STRONG PAIN Plus  
Etc, if more than one product

**1)** 194528 XXX STRONG PAIN Plus

**(L) Product shelf life**

Container description	Bottle
Container material	Glass Type II clear
Closure	Closed
Time	3 Years
Temperature	Store below 25° C
Condition	Protect from light after opening

**(M) Product Specific Conditions**

(The current practise of referencing correspondence in a condition should be discouraged)  
Example : Conditions specified in the letter of 1 December 2004 from Delegate X advising of approval for registration of the goods.

A more appropriate specific condition for where the shelf life is changed from 3 years to 2 years could be:

“You (the Sponsor) is now authorised to market product “product name”, licence number “number” where the licensed conditions have been amended as follows – shelf-life changed from 3 years to 2 years.”

**(N) Product Specific Indications (for Class 2 medicine)**

For the temporary relief of strong pain and discomfort associated with: headache, migraine headache, period pain, muscle pain, backache, neuralgia, rheumatic pain, tension headache, toothache, pain associated with trauma or surgery, symptoms of colds and flu.

**(O) Product Warnings (for Class 1 medicine only)**

- Not to be taken by asthma and allergy sufferers [In 3 mm type, prominent on front]. AND This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers [in 1.5 mm type].
- Not suitable for children.
- Not suitable for infants under the age of twelve months (or words to that effect).
- Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
- This product contains [name of the herb(s) or the chemical component(s)]. Prolonged use may cause serious bowel problems (or words to that effect).
- Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.

**(P) Formulation**

The licence should list the active ingredients with quantities, while the detail of excipient information would be based on Class.

A Class 2 medicine would list excipients with quantity, while a Class 1 medicine will list all excipient information recorded on the register.

*Active ingredient(s)*

Paracetamol	500 mg
Codeine phosphate	10 mg
Doxylamine succinate	5.1 mg

*Excipient(s)*

Cellulose microcrystalline	5.6 mg
Starch maize	30.6 mg
Silica colloidal anhydrous	2.8 mg
Povidone	7.8 mg
Stearic acid	5.6 mg
Magnesium stearate	3.5 mg
Lactose anhydrous	125 mg