20 June 2017

Nicotine Replacement Therapy and the TGA

David Ruschena
General Counsel
Alfred Health

theAlfred

Sandringham HOSPITAL

Part of AlfredHealth

Issues for discussion

- What the TGA does
- How the TGA makes decisions
- How the TGA works with regulators outside Australia
- How the TGA relates to the PBS

The TGA regulates therapeutic goods in Australia.

"Therapeutic goods" are:

1. represented or likely to be taken to be,
2. for therapeutic use or as a component/ingredient in the manufacture of therapeutic good

(or otherwise classified by government as a therapeutic good)

"Therapeutic use" means use in or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
- influencing, inhibiting or modifying a physiological process in persons; or
- testing the susceptibility of persons to a disease or ailment

Therapeutic goods can be either medicines or medical devices.

The TGA regulates the supply, import, export, manufacturing and advertising of therapeutic goods.

The level of regulatory control increases with the level of risk:

- side effects
- potential harm through prolonged use
- toxicity

This is measured against the seriousness of the medical condition.

Regulation takes place through the Australian Register of Therapeutic Goods.

Therapeutic goods must be entered in the ARTG before they can be lawfully supplied in or exported from Australia.

ARTG ID 75233

Product name	ZYBAN SR bupropion hydrochloride 150mg tablet blister pack
Active ingredients	bupropion hydrochloride
Sponsor name	Aspen Pharmacare Australia Pty Ltd
ARTG entry for	Medicine Registered
Public ARTG summary	ARTG ID 75233 - public ARTG summary (pdf)
Product Information	1. PI for ARTG ID 75233 (pdf)
Consumer Medicines Information	1. CMI for ARTG ID 75233 (pdf)

The ARTG specifies approved Consumer Medicine Information.

Zyban® SR tablets

bupropion hydrochloride

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Zyban SR tablets. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Zyban SR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the

Your doctor may have prescribed this medicine for another reason. Zyban SR tablets are not addictive.

Use in children

This medicine is not recommended for use in children less than 18 years because it has not been adequately studied in these patients.

Before you take it

You should be fully committed to quitting smoking before you start

stopped drinking alcohol or you plan to do so while taking Zyban SR

- **you have recently stopped taking tranquillizers (benzodiazepines) or you plan to do so while taking Zyban SR**
- **you have a brain or spine tumour**
- **you are taking any other medicines which contain bupropion**
- **you have or have had an eating disorder (e.g. bulimia or anorexia nervosa)**
- **you are taking medicines called monoamine oxidase inhibitors (MAOIs) or have**

The ARTG specifies approved Product Information.

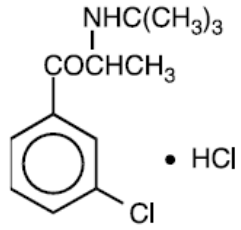
PRODUCT INFORMATION

ZYBAN® SR
sustained release tablets

NAME OF THE MEDICINE:

Bupropion hydrochloride (also known as amfebutamone hydrochloride).

Structure:



The chemical name of bupropion is (±)-1-(3-chlorophenyl)-2-[(1,1-dimethylethyl)amino]-1-propanone hydrochloride. Molecular weight: 276.2 and CAS: 31677-93-7

DESCRIPTION:

ZYBAN SR sustained release tablets contain 150 mg bupropion hydrochloride as the active ingredient. They also contain the excipients microcystalline cellulose, hypromellose, cysteine hydrochloride, magnesium stearate, carnauba wax, opacode WB monogramming ink NS-78-

NRT is regulated as an over-the-counter medicine.

Australia has a two-tiered system for the regulation of medicines, including complementary medicines; registration and listing.

- Registration means that the quality, safety and efficacy of the medicine is assessed.
- Listing means that the quality and safety (but not efficacy) of the medicine is assessed.

Medicines can be listed if they:

- only contain low risk ingredients (in acceptable amounts)
- only relate to non-serious, self-limiting conditions
- make indications for health maintenance and health enhancement

Sponsors can apply to change information or add a new entry.

Changes can be to:

- Name
- Labelling
- Sponsor details
- Therapeutic indications
- Directions for use (including dosage instructions)
- Shelf life / recommended storage conditions
- Safety-related statements
- Consumer information / product information
- Packaging
- Quality control
- Formulation

The TGA provides clear directions in relation to NRT

New NRT dose forms in Australia will require:

- Preclinical (toxicology) data
- Formulation-specific pharmacokinetic data
- Local tolerance data
- Clinical efficacy and safety studies (to justify the intended dosage of the product, including the dose size, frequency and duration of use).

Higher strength NRT products (with the same dosage form), require:

- Preclinical safety data;
- Local tolerance data using the proposed formulation (to demonstrate that the higher nicotine strength does not adversely affect local tolerance); and
- Clinical safety data using the proposed higher strength product formulation.

Changes or new entries involve negotiation before a decision.

Once the sponsor provides the material to the TGA, the TGA assesses the information and comments on whether they are sufficient to justify the changes or additions. These comments may include alternatives.

The sponsor then has an opportunity to respond to the comment.

The TGA then makes a final decision.

Decisions from other jurisdictions (especially Europe and the United States) often form part of these discussions.

The TGA allows the product into Australia; the PBS decides whether to subsidise it

PBS specifies which medicines, and for which indications, the Australian Government will subsidise consumers.

Decisions are made by the Pharmaceutical Benefits Advisory Committee (PBAC).

Where the TGA engages in risk-based regulation, PBAC makes cost-effectiveness decisions. Thus, PBAC decisions will begin with the same analyses that TGA requires regarding effectiveness, but will then require health economic analyses.

Questions?