

## Off label Prescribing Consent Form

In Australia, when it comes to medications, there are three key terms that are important

TGA-approved, PBS-listed, and off-label prescribing

### **TGA Approved**

### **TGA = Therapeutic Goods Administration**

- The TGA is Australia's regulatory body for therapeutic goods, including medicines, vaccines, and medical devices.
- A TGA-approved medicine has been assessed for safety, quality, and efficacy for a specific indication, dose, route, and patient population.
- It means the medicine has passed Australian regulatory standards and is legally permitted to be marketed and prescribed for those specific purposes.

For Example: Metformin is TGA approved for the treatment of Type 2 Diabetes, but is commonly used to treat insulin resistance, the precursor state to Type 2 Diabetes. It is not TGA approved for treatment of Insulin Resistance.

### **PBS Listed**

### **PBS = Pharmaceutical Benefits Scheme**

- The PBS is a government program that subsidises the cost of medicines for Australian residents
- A PBS-listed medicine is not only TGA-approved, but has also been evaluated by the PBAC (Pharmaceutical Benefits Advisory Committee) for cost-effectiveness and public health benefit
- If a drug is PBS-listed, the patient pays only a reduced co-payment (e.g. ~\$30 general or ~\$7 concession), and the government pays the rest
- A drug can be TGA-approved but not PBS-listed, meaning it's legal to prescribe for that condition, but not subsidised, so the patient must pay the full private cost

Example: Ozempic (Semaglutide) is TGA approved, but not yet PBS listed for obesity, so patients have to pay the full price of the drug if it is being used for weight loss

### **Off-Label Prescribing**

- Off-label prescribing refers to the use of a TGA-approved medication, but for a different indication, dose, route, or population than what it was approved for

- Commonly this is because the TGA has not been asked to evaluate the indication. Having a drug TGA approved for a particular condition is costly, and if a drug is off patent, the original manufacturer is unlikely to pay this cost
- In Australia there are currently **no** TGA approved medications for use in patients with POTS, MCAS, MECFS or Long COVID, so all treatments Dr Ryan employs for these conditions will be prescribed in an off-label manner
- However, these drugs have been TGA approved, and PBS listed for other conditions in Australia, and are commonly used
- Off label prescribing is legal and common practice in Australia
- Off-label prescribing must be
  - clinically justified
  - have a favourable risk benefit ratio
  - based on evidence
  - ideally discussed with and consented to by the patient

Example: Naltrexone is TGA approved for alcohol or opioid addiction., However the Royal Australia College of Physicians supports its use as Low dose Naltrexone for patients with Fibromyalgia stating “Despite a lack of robust experimental evidence, preliminary trials and case series in Fibromyalgia, show symptom improvement with LDN and a benign side effect profile

<https://www1.racgp.org.au/ajgp/2023/april/low-dose-naltrexone-in-the-treatment-of-fibromyalg>

If you are being prescribed a PBS listed medicine for an off-label indication, you will have to pay the full cost of the medication, as it will be written as a private script

All medications that are compounded are by definition off label