

# Off-Label prescribing: What is it? Is it legal?

By Dr Giulia D'Anna



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Many practitioners use pharmaceuticals, in particular Dermal Filler and Botulinum Toxin, in an off-label way and don't even know it. For instance, using Botulinum toxin to treat the masseter and temporalis muscle is off-label and not a 'registered' use with Therapeutic Goods Administration (TGA). In fact, those that use Dysport might be surprised to hear that using the drug to treat the horizontal forehead lines is also off-label. So let's look at Off-Label prescribing and define what it is, and also more importantly look at what you need to do clinically to keep both you and your patient safe and informed.

'Off-label' prescribing occurs when a drug is prescribed for an indication, a route of administration, or a patient group that is not included in the approved product information document for that drug on its Australian Register of Therapeutic Goods (ARTG) entry. It is important to note that the Therapeutic Goods Act does not provide regulation for clinicians. So the intention to use a device or medication in an "off-label" way is a decision that the practitioner must make. This is a common area where practitioners get themselves "in-trouble" in the case of an AHPRA complaint, as consent to use a drug in an off-label way needs to be established.

So let's further define the term 'off-label'. 'Off-label' is applied when a medicine is used in ways other than specified in the Australian Therapeutic Goods Administration (TGA) approved product information, including when the medicine is prescribed or administered:

- ◆ for another indication
- ◆ at a different dose
- ◆ via an alternate route of administration
- ◆ for a patient of an age or gender outside the registered use.

## Guidance for off-label use

When the clinician decides to use a drug or device for an off-label treatment, the practitioner should obtain informed consent from the patient, and this should only be done after weighing up the risk-benefit profile, and deciding that there would be a benefit to the patient. The decision to prescribe off-label must take into account the risks and benefits to the patient,



and the evidence supporting the safety and efficacy of the proposed treatment. Some guides have been published by the Council of Australian Therapeutic Advisory Groups, which state that, in the event of harm to the patient, "if the off-label use of the medicine in a particular situation is accepted by the practitioner's peers as constituting competent professional practice, and the patient has given informed consent for its use, then prescribing off-label should not imply negligence."

This means that there must be a significant body of evidence that the use of

a drug in an off-label way has been tested over a period of time, and there is general acceptance by your practitioner peers that such use is considered routine. For example, there are ample studies in the use of Botulinum toxin for the treatment of masseter hypertrophy and bruxism. Although this evidence exists, this does not preclude the practitioner from the responsibility to inform the patient of the off-label use of the drug.

Each Botulinum Toxin drug has particular TGA listed use. The On-label uses are listed in Table 1 below:

Off-Label Use		
BOTOX	XEOMIN	DYSPORT
<p>Many medical reasons - see ARTG register for the full listing.</p> <p><b>Cosmetic listing on TGA:</b> Temporary improvement in the appearance of upper facial rhytides (glabella lines, crow's feet &amp; forehead lines) in adults.</p>	<p>Xeomin is indicated in adults for the treatment of:</p> <p>Cervical Dystonia Blepharospasm Spasticity of the upper limb</p> <p><b>Cosmetic listing on TGA:</b> Upper facial Lines Glabella Frown Lines Lateral Periorbital lines Horizontal Forehead lines</p>	<p>Dysport for symptomatic treatment of focal spasticity:</p> <p>upper &amp; lower limbs in adults Upper limbs child 2+ years Lower limbs child 2+ years Adult treatment of Spasmodic torticollis Blepharospasm Hemifacial spasm</p> <p><b>Cosmetic listing on TGA:</b> Moderate to severe glabella lines and/or lateral canthal lines</p>

Table 1

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This means that any use outside of these listings, is off-label. In determining the appropriateness of using a medicine off-label, there should be sufficient evidence to support its efficacious and safe use, and an overall favourable harm: benefit ratio for the intended clinical use and population. This means that you should only use TGA-listed drugs for off-label indications if there is a good body of evidence for the off-label use. Off-label use is very common with Botulinum Toxin drugs, as well as many other drugs.

The use of a cannula with Dermal Filler is also considered off-label, as the delivery method for the drug is different than the ARTG listing. However this is the safest delivery method, and is considered medical standard in cosmetic injecting. That aside, you still need to gain consent from your patient in both the treatment itself, but the use of an off-label delivery method.

### Is off-label use legal?

The short answer is 'Yes', if there is a large body of evidence that states that the benefit outweighs the risk to the patient, and that it is generally accepted amongst your peers. If we look at the use of a cannula with dermal filler, for example, the safety profile is very beneficial for the patient.

Dr Lee Walker, a global speaker on cosmetic injecting and also a dentist from the UK, recently stated (March 2022) that the use of a needle with Dermal Filler is associated with a risk of 1:6000 of a vascular incident. However, if you deliver dermal filler with a cannula, the risk becomes 1:40,000. It makes total sense to use Dermal filler via off-label cannula delivery when you consider this statistic, especially since there are an overwhelming number of studies that are high-quality and patient based that also support this statement.

To assist practitioners, a number of professional organisations have issued



guidance in relation to off-label medicine use. It is accepted practice that the prescribers should inform patients and document consent when prescribing off-label, including an open discussion about known and unknown benefits and risks. It is important that the prescriber documents the reason for off-label use in the patient's record and ensures that patients are aware of the treatment procedure, along with any reviews that may be required.

I have included here a flowchart adapted from the Council of Australian Therapeutic Advisory group to help you decide whether using a pharmaceutical off-label is warranted and ethical (Table 2).

### Why don't pharmaceutical companies obtain more listings?

One reason for persistent high rates of off-label use of pharmaceuticals amongst

practitioners, is the lack of incentives for pharmaceutical companies to seek approval for additional indications, particularly if there is unlikely to be any additional revenue for the company. When you consider the time and cost of undertaking additional research and obtaining regulatory approvals to have each new use listed on the ARTG register, this would run into millions of dollars for a single drug. So once a drug is available on the TGA register, pharmaceutical companies often have little incentive to invest more time and money and research into more on-label uses for the drug, as they rely on practitioners to make sensible use of the drugs, and undertake the proper consenting.

### Where to from here?

You must inform your patient of the off-label use of any pharmaceutical or device that you plan to use in the patient treatment, to ensure that they understand that you are modifying the TGA-listed use. Should there be an adverse event following off-label use, this may be a potential legality that would be hard to defend if the patient was not informed prior to treatment. I encourage you to include off-label use of pharmaceuticals in your consenting process, as well as on your consent forms, particularly when it comes to the use of Botulinum Toxin and Dermal fillers. ♦

If you would like to learn more about the use of Botulinum Toxin and Dermal fillers, especially with the use of safer cannula-use, visit: [www.dermaldistinction.com](http://www.dermaldistinction.com)

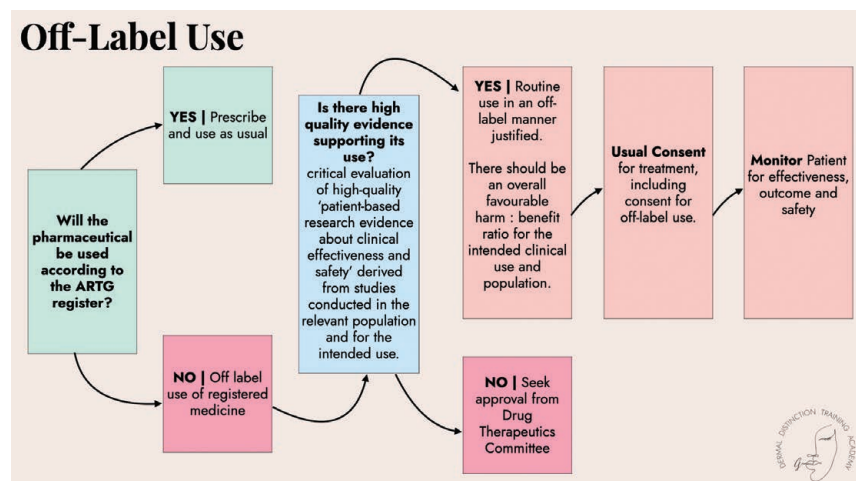


Table 2