

Don't risk your registration!

Only buy approved products and support the Australian dental industry (Part 1)

What our family dental practice has learnt and how it can help you:

1. Buying from overseas, on-line or non-TGA registered products can jeopardies your registration
2. Using a product that is not on the ARTG exposes you legally, professionally and personally, the exception is a compounded product from a pharmacy
3. It's tough for Australian companies to get TGA registration so you need to support them if you want more and better products
4. Not buying locally will mean you do not get local support
5. What to do – do an audit today – ensure you or your team are not buying inappropriately

The ADIA (Australian Dental Industry Association) has great information on this topic and much of this article is relaying what they have on their website you should keep up to date with this if you run a practice and order product see: <https://www.adia.org.au/for-dental-professionals/imports>

Importing products yourself is easy but not allowed

We've talked to dental wholesalers and the dentists who bring in product are becoming a real problem. Thanks to the internet, it is easier than ever before for dentists and our teams to get our hands on anything around the globe including importing dental products from overseas.

Purchasing dental products online is often cheaper than purchasing products from distributors in Australia. However, in most cases if a dentist and our teams purchase dental products, these products can't be used on patients. To do will risk being prosecuted by the Australian Government and in many cases insurers will not cover you when using products from overseas – you may even have your professional registration suspended or cancelled.

The following questions are common amongst dentists and allied oral healthcare professionals seeking to import dental product.

Dental products are regulated for a reason – safety is the key

The majority of the products and materials we use in our practice today are classified as therapeutic devices under the Therapeutic Goods Act 1989 (Cth) and subordinate regulations administered by the Therapeutic Goods Administration (TGA). The legislation refers to those products that are used for humans; have therapeutic benefits; generally have a physical or mechanical effect on the body; or are used to measure or monitor functions of the body. So nearly everything we use in the practice.

The type of product falling within the scope of the regulations includes not only many common products used in dentistry such as braces, fillings, and dental tools such as syringes, but also a range of equipment including dental chairs, sterilisers, and X-ray machines through to instruments such as dental hand-pieces and forceps. The regulations also cover a wide range of mainstream healthcare equipment and products including artificial hips, blood pressure monitors, breast implants, catheters, lubricating eye drops, and tongue depressors.

Dentists can import medical devices for use in their practice – but ...

Dentists who import medical devices for use in their clinical practice are considered to be supplying the devices to the general public. Examples of importing dental products which fall within the legal definition of supplying the products includes purchasing from overseas on-line or from mail order catalogues, or obtaining from international conferences and trade exhibits.

Can dentists import medical devices under the personal importation provisions?

Dentists can import medical devices under the personal importation provisions but not for use in their clinical practice (i.e. not for use on patients). The personal importation scheme can only be used to import a medical device for personal use or for the treatment of immediate family.

A common misunderstanding amongst dentists and allied oral healthcare professionals is that the TGA approves dental products. This isn't the case, which has implications when considering importing products – just because a product is already available in Australia doesn't mean that you can import the same product (even from the same manufacturer) and use it on patients. If you import the product, you are responsible for having it listed within the Australian Register of Therapeutic Goods (ARTG).

The only exception is compounded product ordered from a compounding pharmacy for use on your patients. You need to keep good clinical records and follow the APHRA guidelines.

The bottom line

Just don't risk it. Our family has run our family practice for nearly 30 years and has provided services to other practice for 25 years. We are now going through the TGA process to ensure the products we supply other practices are safe. This is expensive and takes years. So if you cut corners and bring in products yourself or your team does then you hurt local Australian businesses and risk your own livelihood.

The regulatory standards for the supply of medical devices in Australia are complex and need to be met by all businesses supplying product in Australia. That is part of the reason that products available through suppliers in Australia are more expensive than those bought via on-line – there is a considerable burden associated with regulatory compliance costs. Buy locally, Acumen Dental provides YUM Bubblegum topical and other local products go to <http://acumen.dental> for more information

In the next article we cover your responsibilities if you decide to buy online or import yourself. ♦

Dr Mike Ryan DBA heads up Acumen Dental who bring you YUM Bubblegum topical gel, Dental Prescribing and Dispensing go to www.acumen.dental to request order forms – they can be contacted at info@acumen.dental or fax to 03 9568 2885 or write to PO Box 608, Carnegie 3163



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PRODUCT	EACH	QTY	TOTAL
YUM Bubblegum™ Standard - 50mL 15% Lidocaine	\$77.00		
Subtotal (ex.GST) \$			
GST \$			
Total (inc. 10% GST) \$			

COMPOUNDING PHARMACY ORDER

WHAT ARE YOUR DETAILS? WHERE DO WE SEND IT?

This service operates from our family dental practice to support your practice

CONTACT DETAILS / DECLARATION	
Dentist Name	Prescriber No.
<input type="text"/>	<input type="text"/>
Email	
<input type="text"/>	
Fax	Phone
<input type="text"/>	<input type="text"/>
Practice Address	Postcode
<input type="text"/>	<input type="text"/>
I declare that the information provided on this document to be true and correct.	
Contact Name	Dentist's signature
<input type="text"/>	<input type="text"/>

PAYMENT INFORMATION	
HOW WOULD YOU LIKE TO PAY?	
Payment must accompany order - we do not have accounts. GST will be added to your order. Free Delivery over \$250 (otherwise include \$9.90+GST)	
Visa <input type="checkbox"/> MasterCard <input type="checkbox"/> Cheque <input type="checkbox"/> Direct Debit <input type="checkbox"/>	
Card No.	<input type="text"/>
Expiry Date	Name on Card
<input type="text"/>	<input type="text"/>
Cardholder's signature	<input type="text"/>
Would you like us to keep payments details on file? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Bank Deposit : Pay directly and send payment confirmation with order Acumen Dental BSB: 083-152 Account: 18-727-5636	

Thank you for your order, please return this form to:

Fax (03) 9568 2885 **Post** PO box 608 Carnegie, 3163 **Email** info@acumen.dental