Professional help to **legitimize dental imports**

Roy Hardman is the go-between guy for TGA accreditation of medical devices

By Danny Chan

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Importing a dental device or pharmaceutical product into Australia involves a structured but potentially cumbersome process. From the onset, the local agent or distributor bringing in such a product needs to make an application to have the good(s) entered in the Australian Register of Therapeutic Goods (ARTG) – assuming of course, the product is not an excluded good.

Established under the Therapeutic Goods Act 1989, the ARTG is a computer database of information about therapeutic goods – a broad classification for both medicines and medical devices. As set out by the Therapeutic Goods Act, Regulations and Orders, requirements for inclusion on the ARTG cover advertising, labeling, product appearance and appeal guidelines. These factors concomitantly determine whether or not the good in question may be approved for supply in, or export from, Australia.

The Therapeutic Goods Administration (TGA) is a unit of the Australian Government Department of Health and Ageing that is responsible for administering the provisions of the legislation. To ensure therapeutic goods available in Australia are of an acceptable standard, the TGA carries out a range of assessment and monitoring activities.

Before submitting an application, both sponsor and product manufacturer need to be aware of the extensive requirements involved and be prepared to assume legal responsibilities. Beyond observing form-filling protocols, the challenges are in carrying out due diligence in research and paperwork, as well as understanding the regulatory framework.

Fortunately, there are professionals you can turn to for help. Meet Roy Hardman, also known as a TGA Accreditation Specialist Agent for Medical Devices. Roy is Managing Director of Right Time Business, a company that assists dental and medical manufacturers to understand and comply with the requirements of TGA in Australia. As the longer title suggests, Roy guides companies and individuals who wish to have their devices included on the ARTG. He also helps clients better understand how TGA regulations can impact their work requirements and the obligations of being a sponsor.

Advocating an "open and honest" approach to earning the accreditation, Roy advises:

"You need to understand the market and be registered correctly as a sponsor. There must also be a willingness to understand the requirements outside of the TGA regulatory system. Avoid guessing the classification of device or submitting a duplication device. If necessary, you must be willing to address the needs of a recall."

By qualification, Roy is a professional business marketer and specialist. His work experience ranges from Sales Representation; and National Sales and Marketing Management; to General Management for International and Australian Companies. He is also a lecturer in Marketing and a registered agent with TGA in Australia as well as WAND (Web-Assisted Notification of Devices) in New Zealand.

Roy's training and background is as extensive as it is diverse: Biology (Bachelor of Science); Pharmacy (Masters of Applied Science); Marketing (Graduate Diploma); Business Administration (Graduate Diploma); as well as certificates in Sales Management, Sales Team Development, Sales Manager Challenges and Work Place Training and Assessment (Cert IV). Roy is also completing a Masters in the health area that will be converted to a PHD (doctorate) in 2011.

He neatly sums up his field of expertise as "the science of understanding people's needs within the industry sector that I work."

"I believe elements from all the areas of my training contribute to my work. I need to understand the biological nature of how devices work in the body as well as its chemical components, both addressed by my training in biology and pharmacy.

"My sales and marketing background assists in business development and helping clients with letters and advice. My knowledge in workplace training and assessment helps me guide and instruct product managers on the technical requirements of TGA and WAND (New Zealand's Web-Assisted Notification of Devices)."

True to his company name, Roy was timely placed to become a TGA Registered Agent. His background in pharmaceuticals and work


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within the dental and medical industry for more than 20 years has paved his way to specialize in government contracts and tenders. When the TGA legislation was introduced in 2002, Roy found himself ideally positioned to assist companies that needed to comply with the new regulations.

"I had the skill level to guide and understand, rather than tell, people what needed to be done. As a cooperative part of the company's team, I was able to integrate well and there was, and is, no conflict of interest.

"I believe it's a good fit as this work needs a person who is focused and ensures that every effort is made to be correct. I have the ability to assimilate large amounts of technical information and interpret/translate the information in a way that people I work with can understand and appreciate. I also enjoy the technical mind games that dealing with such legislation requires."

Roy takes a hands-on approach to guiding customers throughout the sponsorship process. Besides reviewing paperwork and seeking confirmation from the overseas manufacturers, he ensures that all requirements to include a device on the ARTG are in agreement with the device legislation. In short, he takes over the role of preparing and submitting the application with TGA: Obtaining all necessary documentation via cooperation with the Australian sponsor to satisfy and comply with TGA regulations; discussing all issues relating to the application; assessing audit requirements; reviewing classification; and ensuring that all conformity is adhered to in accordance with the legislation.

More importantly, he gives proper guidance on the interpretation of the legislation. The former Chair of Regulatory Affairs with Australian Dental Industry Association (ADIA) is well equipped to present – and argue – a case from the client's perspective, while serving as legislative guide to aid in the client's compliance with his/her legal obligations. He adds: "I become a part of their team as I have no conflict of interest, and am not a sponsor."

Rather than make hasty decisions, Roy urges those interested to find out more about sponsorship and TGA requirements. One of the frequently neglected aspects in the sponsorship process, he cautions, involves the failure to understand classification rules – and how devices are grouped – which can result in duplication of costs.

"I have audited many companies that have spent a fortune with TGA not understanding how to classify devices or group them. It is not the TGA's role to assist in reducing duplication in ARTG entries.

"Many dentists/individuals/companies that I have assisted now understand the TGA's fee structures and have decided not to import devices into Australia. Many people do not understand that there are ongoing TGA fees over the life of the device or how financial this commitment can be." ◆

For more information on TGA Accreditation, contact Roy Hardman at: roy@righttimebusiness.com.au
On behalf of dental companies at IDS Cologne in 2011, Roy provides representation with existing and potential suppliers.