# Country of Origin Labeling for Dental Appliances.

Dental devices are custom manufactured prostheses to suit individual patients. This includes products such as Crowns, Bridges, Dentures and some Implant components. All these products together with many consumables used in the Dental Industry are classified as Medical Devices. This is a very broad class of medical products and we refer to them as Dental Appliances to distinguish them appropriately.

It is generally considered that approaching 50% of these custom devices are sourced from overseas markets such as China, India and Vietnam. From a TGA perspective, custom medical devices are not validated at the source of manufacture; the onus is on the practitioner using them to verify that they are of an adequate standard. However the practitioner ordering them is often unaware of the source of origin and is simply not in a position to take this responsibility; they simply cannot know what is in the prosthesis. The Importers of these Dental Appliances are intermediaries and they are often badged as Australian icons. They promote heavily and use untruths and misleading statements to confuse practitioners.

The situation in Australia is considered inadequate. Practitioners are uncertain as to the actual source of manufacture since the product is ordered from a Laboratory with an Australian address. Patients are similarly unaware of where their Dental Appliance is manufactured. For some, the reduced cost of an offshore Dental Appliance may appeal since it reduces overall treatment cost; others unfortunately pay the full treatment fee yet receive an offshore product.

Adopting a system of labeling or disclosure of the manufacture source would benefit both patients and practitioners. Patients are consumers and have a right to make an informed decision. There is no difference between the foods we consume, which is covered by legislation in this regard, and a Dental Prosthesis, which is effectively implanted in the mouth. Yet one must comply with the Food Standard Code whilst the other is free from any form of disclosure. The UK Government for example has responded to this by offering patients receiving a Dental Appliance a copy of the statement of manufacture. Practitioners are obligated to retain this statement for the lifetime of the Prosthesis and record whether this was provided to the patient or not.

We would benefit from Federal legislation in Australia such that if a dentist or other dental care professional decides to sub-contract the manufacture of a Dental Appliance outside Australia, they will be held professionally accountable for the safety and quality of this appliance. The statement of manufacture would serve as proof to both patient and practitioner of the country of origin.