NSW TAG RESPONSE TO THE CONSULTATION: DRAFT CLINICAL EVIDENCE GUIDELINES - MEDICAL DEVICES Version 1.0, March 2016

These Clinical Evidence Guidelines fail to adequately describe the necessary information for the critical evaluation of devices or equipment that are associated with medicines use or that contain medicines. These include but are not limited to administration equipment e.g. implantable devices, elastomeric devices such as Pain Buster™, insulin pumps, intravenous infusion lines; drug-eluting or-impregnated technology such as stents and dressings; dose administration aids and automated dispensing cabinets. The lack of critical evaluation by health care professionals with appropriate expertise in the assessment of safety and efficacy of medicines and medicines regulation regarding such devices and equipment may place patients at harm. The post-marketing safety monitoring of these devices should also incorporate a pharmacovigilance perspective. This is particularly pertinent to devices that contain medicines that are scheduled, when the medicines is not registered or is being used in an off-label manner. Currently any employee can order devices and equipment within the NSW hospital system. Furthermore, they may not be comprehensively reviewed within the hospital system prior to use as there is confusion amongst clinicians about the evaluation and governance role of Drug and Therapeutics Committees for devices/equipment and their local use may not be appropriately monitored for effectiveness and safety.

Drug administration equipment
This equipment forms an integral part of the administration of the correct dose of medications over an appropriate timeframe. The potential for patient harm can be illustrated by elastomeric devices e.g. Pain Buster™ which are used to provide post-operative analgesia. These devices provide continuous infusion of a local anaesthetic into an intra-operative site for 24 to 48 hours. It is inserted intra-operatively and is not easily visible. There are reports of these devices being reloaded in outpatient clinics. These devices have the potential to cause anaesthetic toxicity from mild symptoms of restlessness and confusion to more serious adverse effects such as cardiac arrhythmias and respiratory and cardiac arrest. However the drug and dose that is being administered to the patient may not be documented because these interventions are seen as ‘devices’ rather than medicines and, if documented, the information is likely to be found on intra-operative records with relevant information transfer to areas such as outpatient clinics unlikely. As these interventions are classed as devices they do not undergo the critical evaluation that a Drug and Therapeutic Committee (DTC) would provide when a local anaesthetic is administered by other means e.g. a
regional block using local anaesthetic would be written on a medication chart and have a local protocol with oversight by the DTC. Although it could be said that a hospital has the ability to have policies that would mean medication-associated devices should also be evaluated by their DTC, this is less likely and liable to meet barriers when the TGA, as the Australian regulator, does not evaluate these devices from the medicine perspective as well as the device perspective. Additionally, there is the potential for devices that administer medicines to have drug interactions that will not be easily identified if they are not documented in an appropriate place.

Factors such as temperature, volumes and rates of delivery of a wide variety of medicines for drug administration devices need to be considered when assessing these devices. Patient harm has occurred when these aspects have not been considered with failed delivery of medicine or medicine deterioration. Character limits when describing drugs on equipment require consideration. Nasal administration devices for the delivery of medicines also require assessment from the device and medicines perspective.

**Drug-eluting or impregnated technology**

This technology has the potential for both individual patient and environmental harm, and increased financial burden to the healthcare system if it remains unchecked. In particular devices which elute antimicrobial agents should be required to undertake stringent studies into efficacy and harm for individual patients, and into the impact of indiscriminate low dose antimicrobials on the resistance of microorganisms in the environment, particularly in hospitals. Examples include antibiotics in bone cements and burns dressings.

We recommend that these devices be approved through the Therapeutic Goods Authority not as therapeutic devices but as therapeutic drugs, according to the drug they are eluting. Alternately there could be a separate classification in the therapeutic goods register for devices which elute therapeutic drugs.

**Dosage administration aids and automated dispensing cabinets**

These devices have the potential to cause patient harm if not fit for purpose. Whilst market forces would potentially limit inappropriate products, evaluation by health care professionals with the relevant expertise prior to registration should be undertaken.

**Technology e.g. software programs**

Technology such as software programs that provide e.g. dosing nomograms of scheduled medicines should also be considered for national regulation. Although this would be challenging, parameters could be provided to identify the technology that has the potential to lead to serious patient harm and require initial and ongoing oversight and evaluation. Again, market forces may not limit the uptake of these products by end-users prior to serious harm occurring.

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**Promoting the quality use of medicines**

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Unregistered devices
On rare occasions, requests are received by hospitals to obtain unregistered devices (may or may not be medicine-related). It appears that there is no devices program similar to that of the Special Access Scheme and authorisation of prescribers for unregistered medicines. We would recommend consideration of such a scheme and incorporation into guidelines if this is considered an appropriate means of acquisition.

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