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COMMENT ON THE ACA PROPOSALS PAPER:
***Planning for Medical Implant Communications Systems (MICS) & Related Devices, October 2003*.**

Thankyou for the opportunity for the TGA to comment on the ACA planning proposals in relation to the operation of MICS equipped devices in Australia, as described in the above Proposals Paper.

Over the last year there have been several telephone conversations and email correspondence between staff of the TGA and the ACA in relation to MICS, triggered by an application by a medical device supplier to enter an implantable device with limited MICS capability on the Australian Register of Therapeutic Goods. That application was subsequently rejected by the TGA on the basis that evidence was not provided to demonstrate that MICS would perform as intended in the Australian environment. This was a rejection of the available evidence for that particular product and not a rejection of MICS in general.

The TGA welcomes the ACA proposal to introduce regulatory arrangements that would support the operation of fully MICS compliant devices in Australia. It is noted that this is proposed to be on a no-protection no-interference basis. This necessarily limits the uses to which this technology can be reliably applied, but this is consistent with the arrangements in place in other countries where MICS currently operates.

The analysis in the Proposals Paper appears generally sound. However, the following issues should be considered:

- The analyses assume that external MICS programmer/controller equipment will be located in hospitals or specialist medical clinics. This assumption contributes to the conclusion that interference between MICS equipment and offshore radiolocation and land mobile systems (LMS) will be unlikely. However, MICS applications and products in which the external programmer/controller equipment is mobile or based in patients' homes are quite likely. An example of such a system is the implantable device with limited MICS capability described above.
- The analyses assume that MICS usage in remote areas will be unlikely. This appears to be based on low population densities and on the previous assumption described above. This may be valid in the broadest sense, however the paper does not consider the consequences for rural or remote patients with MICS-equipped implants. In particular, mobile MICS service coverage may be geographically limited in practice.

- The proposal allows MICS implants to normally transmit only when communications are initiated by programmer/controller equipment. However in the case of "medical implant events" the implant is allowed to initiate communications. The Proposals Paper does not take into account the potential nature of these "medical implant events", which may often indicate an imminent life-threatening condition for the patient. Furthermore, there is no consideration of the associated MICS service coverage, reliability and trustworthiness issues.

The concerns expressed above should however be largely mitigated by the ability of fully MICS compliant devices to select from a range of available radio frequencies. If one or more of the MICS frequencies are in use in a particular locality, the programmer/controller can select a different frequency that is not in use.

The implantable device previously referred to appears to incorporate only part of the MICS specification. In particular, the system does not appear to fully implement the frequency agility requirements. For the reasons outlined above, the TGA is concerned about the safety and performance of these kind of one-way fixed-channel telemetry systems for medical implants. The TGA therefore has no objection to the ACA proposal to limit any new spectrum regulatory arrangements to fully compliant MICS devices, without allowance for one-way fixed-channel implant telemetry systems.

There is a residual risk that MICS service coverage, reliability and trustworthiness may be limited even for systems that fully comply with the MICS requirements. There may be rare instances or localities in which heavy use of the MICS radio spectrum makes implant telemetry unreliable. "Medical implant event" transmissions, because of their nature, may also not necessarily employ frequency agility techniques. The machine intelligence necessary for frequency selection will generally reside in the programmer/controller, rather than in the implant that is initiating the communication session.

The TGA therefore has some concerns about the ACA MICS proposal, but the MICS specification appears to reduce the risk to patients to an acceptable level, and the potential benefits are likely to exceed the risks for fully compliant MICS devices. Nonetheless, patients and their physicians should be made aware that the no-protection no-interference support for MICS equipped devices in Australia may result in limited service coverage in some localities and instances. Provided that this can be addressed, the MICS proposals should benefit Australian patients.

For further discussion on any of these issues, please contact John Jamieson.

Yours sincerely,

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