Statement of the Communications Authority

Variation to the Class Licence for Medical Implant Communication System Device under Section 7C of the Telecommunications Ordinance (Chapter 106)

27 September 2019

INTRODUCTION

On 5 July 2019, the Communications Authority ("CA") published a consultation paper entitled "Variation to the Class Licence for Medical Implant Communication System Device under Section 7C of the Telecommunications Ordinance (Chapter 106)" (the "Consultation Paper")[1]. A Gazette notice was published on the same day announcing the issue of the Consultation Paper. The CA proposed in the Consultation Paper to vary the Class Licence for Medical Implant Communication System Device (hereinafter referred to as the "Class Licence") to expand its scope to cover, in addition to Medical Implant Communication System ("MICS") devices operating in the 402 – 405 MHz band (hereinafter referred to as "existing MICS devices"), MICS devices operating in the 401 – 402 MHz and 405 – 406 MHz bands (hereinafter referred to as "the additional frequency ranges"); and to cover the possession, use and trading of all MICS devices operating in the 401 – 406 MHz band. The proposal would help embrace more MICS devices to meet the specific medical needs of medical practitioners and patients, and facilitate the trading activities for such devices. The CA invited interested parties to give views and comments on its proposal. A submission[2] from Medtronic Hong Kong Medical Limited ("Medtronic") was received by the close of the consultation period on 2 August 2019.

RELEVANT STATUTORY PROVISIONS

2. Pursuant to section 7C(1) of the Telecommunications Ordinance ("TO") (Cap. 106), the CA may vary the conditions of a class licence by notice in the Gazette. Pursuant to section 7C(2) of the TO, the CA may in varying a class licence –

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[1] See http://www.coms-auth.hk/filemanager/en/content_711/cp20190705_e.pdf

[2] The submission is available at: https://www.coms-auth.hk/en/policies_regulations/consultations/completed/index_id_519.html

(a) specify further telecommunications networks, systems, installations or services that a person may supply under the licence;

(b) vary or revoke the type of telecommunications network, system, installation or service that a person may supply under the licence;

(c) add conditions to the licence; and

(d) vary or revoke conditions in the licence.

3. Pursuant to section 32D(1) of the TO, the CA may prescribe standards and specifications of –

(a) telecommunications networks, systems, installations, customer equipment and services;

(b) other non-telecommunications equipment generating, deliberately or incidentally, radio frequency energy that may cause interference to telecommunications networks, systems, installations, customer equipment and services; and

(c) other non-telecommunications equipment that may suffer interference from telecommunications networks, systems, installations, customer equipment and services.

SUBMISSION RECEIVED AND CA'S RESPONSES

4. Medtronic does not have any objection to the CA's proposal to vary the Class Licence. However, it proposes the following amendments to the draft varied Class Licence and the draft revised specification HKCA 1052, i.e. Appendices 1 and 2 respectively to the Consultation Paper –

(a) to change the power limit of 25 μW equivalent isotropically radiated power ("EIRP") to 25 μW effective radiated power ("ERP") as specified in the draft varied Class Licence and the draft revised specification HKCA 1052, which is in effect relaxing the power limit[3];

(b) to change the term "*programmer/control transceiver*" as specified in the draft varied Class Licence to "*programmer/peripheral*";

[3] EIRP equals to 1.64 × ERP. As such, 25 μW ERP is equivalent to 41 μW EIRP.

(c) to update the standards published by the European Telecommunications Standards Institute under reference in clause 3 of the draft revised specification HKCA 1052, but specifying the titles and version numbers of these standards should not be necessary; and

(d) to add additional international safety standards specifically for implantable MICS devices under reference in clause 2 of the draft revised specification HKCA 1052.

5. After careful consideration, the CA generally agrees to Medtronic's proposals subject to some editorial improvements. Details of the submission from Medtronic and the responses of the CA are at **Annex**.

THE CA'S DECISION

6. Having considered the submission received and the fact that MICS devices operating in the additional frequency ranges are available on the international market, the CA considers that the proposed variation to the Class Licence would be beneficial to the medical practitioners, the patients and the concerned equipment suppliers in Hong Kong. As such, the CA decides to –

(a) vary the Class Licence as set out in Appendix 1 of the Consultation Paper with –

(i) the maximum power specified in the Schedule to the Class Licence changed from 25 μW EIRP to 25 μW ERP; and

(ii) the term "*programmer/control transceiver*" specified in the Class Licence changed to "*peripheral*"; and

(b) adopt the revised specification HKCA 1052 as set out in Appendix 2 of the Consultation Paper with the following additional amendments –

(i) change the maximum power limit specified in clause 3 of HKCA 1052 from 25 μW EIRP to 25 μW ERP;

(ii) update the list of standards to EN 302 537 for MICS devices operating in the additional frequency ranges, and EN 301 839 for the existing MICS devices under reference in clause 3 of HKCA 1052; and

(iii) include additional safety standards specifically for implantable MICS devices, i.e. ISO 14708-1 and EN 45502-1, under reference in clause 2 of HKCA 1052,

with effect from the date of this statement.

7. To implement the CA's decision, the Office of the Communications Authority ("OFCA") publishes the varied Class Licence in the Gazette in accordance with section 7C(1) of the TO and adopts the revised specification HKCA 1052 today. For public access, the varied Class Licence is available on the CA's website (http://www.coms-auth.hk/en/licensing/telecommunications/class/index.html) and the revised specification HKCA 1052 is available on OFCA's website (http://www.ofca.gov.hk/en/industry_focus/telecommunications/standards/hkca/radio_equipment_specifications/index.html).

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Annex

Details of the Submission and the CA's Responses

Item	Industry's Views	CA's Consideration and Responses
1	**Medtronic** proposes to change the power limit of 25 μW EIRP to 25 μW ERP as specified in the draft varied Class Licence and the draft revised specification HKCA 1052. Note: EIRP equals to 1.64 × ERP. As such, 25 μW ERP is equivalent to 41 μW EIRP. Medtronic's proposal is in effect relaxing the power limit.	The former Telecommunications Authority ("TA") conducted a public consultation in December 2007/January 2008 on the proposed creation of a Class Licence for MICS devices, i.e. the existing Class Licence. The TA proposed a power limit of 25 μW EIRP for MICS devices with reference to an analysis for sharing the 401 – 406 MHz band[1] between MICS devices and meteorological aids service given in Recommendation ITU-R RS.1346[2]. With no adverse comment received, the TA approved to create the existing Class Licence which adopted the power limit of 25 μW EIRP in 2008. Medtronic proposes to change the power limit to 25 μW ERP, i.e. the power limit for MICS devices as adopted by the European Conference of Postal and Telecommunications Administrations ("CEPT"). Notwithstanding that Medtronic's proposal actually increases the absolute power limit by 1.64 times, there is no interference report in this regard as per CEPT's experience. By adopting Medtronic's proposal, the Class Licence will cover more MICS devices and result in wider choices of equipment to better serve Hong Kong users. Medtronic's proposal is therefore agreeable to the CA. The varied Class Licence and the revised specification HKCA 1052 has been updated accordingly.
2	**Medtronic** proposes to change the term "*programmer/control transceiver*" used in the Schedule to the draft varied Class Licence to "*programmer/peripheral*".	"*Peripheral*" is a generic term for equipment outside the human body that communicates with a medical transceiver implanted inside or worn on human body and generally includes *programmer, control transceiver,* etc. Medtronic's proposal is agreeable to the CA. The varied Class Licence has been updated to adopt the term "*peripheral*" in place of "*programmer/control transceiver*".

[1] The 401 – 406 MHz band is allocated to, among other services, meteorological aids service and part of this band is being used by such systems in Hong Kong.

[2] Entitled "Sharing between the meteorological aids service and medical implant communication systems (MICS) operating in the mobile service in the frequency band 401-406 MHz".

Item	Industry's Views	CA's Consideration and Responses
3	**Medtronic** proposes to update the standards published by the European Telecommunications Standards Institute ("ETSI") under reference in the draft revised specification HKCA 1052, but specifying the titles and version numbers of these standards in HKCA 1052 should not be necessary.	ETSI published the relevant standards of MICS devices in two parts, i.e. EN 301 839-1 and EN 301 839-2 for the 402 – 405 MHz band as well as EN 302 537-1 and EN 302 537-2 for the 401 – 402 MHz and 405 – 406 MHz bands, until 2016 where the respective relevant parts were combined into one to form EN 301 839 and EN 302 537 respectively. Meanwhile, the version of the said standards in force is V2.1.1. The CA noted that Medtronic's proposal has nil effect on the substance of the technical requirements and is in line with the prevailing practice of HKCA specifications where version numbers of the reference standards are generally not specified. Medtronic's proposal is agreeable to the CA except that the titles of these standards should be specified for the sake of clarity and in consistency with the prevailing practice of HKCA specifications. The revised specification HKCA 1052 has been updated accordingly.
4	**Medtronic** proposes to add additional international safety standards specifically for MICS devices to the draft revised specification HKCA 1052.	Among different safety requirements, consistent with the existing Telecommunications Ordinance (Cap. 106), only electrical safety for MICS devices is relevant under clause 2 of the original and the revised specification HKCA 1052. In this connection, Medtronic's proposal to include also the electrical safety requirements of the widely adopted international standards of ISO 14708-1 and EN 45502-1[3] for implantable MICS devices is agreeable to the CA. The revised specification HKCA 1052 has been updated accordingly.

[3] The electrical safety requirements and the associated conformity check procedures specified in ISO 14708-1 and EN 45502-1 are largely the same.