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Details of Filing

Document Lodged:	Concise Statement
File Number:	NSD883/2021
File Title:	SECRETARY OF THE DEPARTMENT OF HEALTH v MEDTRONIC AUSTRALASIA PTY LTD ACN 001 162 661
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA

Dated: 31/08/2021 3:19:48 PM AEST Registrar

Important Information

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CONCISE STATEMENT

FEDERAL COURT OF AUSTRALIA
DISTRICT REGISTRY: NEW SOUTH WALES
DIVISION: GENERAL **NO NSD OF 2021**

SECRETARY OF THE DEPARTMENT OF HEALTH
Applicant

MEDTRONIC AUSTRALASIA PTY LTD (ACN 001 162 661)
Respondent

A. INTRODUCTION

1. This proceeding is brought by the Secretary of the Department of Health (the **Secretary**) under s 42Y(1) of the *Therapeutic Goods Administration Act 1989* (Cth) (the **Act**). It concerns the unlawful supply by Medtronic Australasia Pty Ltd (**Medtronic**) of therapeutic goods for use in humans that were not registered on the Australian Register of Therapeutic Goods (the **ARTG**).

2. Between 1 September 2015 and 31 January 2020 (the **Relevant Period**), Medtronic supplied 16,290 units of the INFUSE® Bone Graft Kit (the **Kit**), to 108 hospitals, notwithstanding that the Kit was not registered on the ARTG. Each of those instances of supply was in contravention of s 19D(1) (alternatively, s 41MIB(1)) of the Act, as in force during the Relevant Period.

3. The Kit was supplied without the Secretary having had the opportunity to evaluate its suitability for registration on the ARTG by reference to the applicable statutory criteria, including its quality, safety and efficacy as a stand-alone therapeutic good.

B. IMPORTANT FACTS GIVING RISE TO THE CLAIM

The Device, but not the Kit, included on the ARTG

4. At no time during the Relevant Period was the Kit registered on the ARTG.

5. Instead, there was included on the ARTG a therapeutic good of which the Kit formed one part: namely, the 'Infuse Bone Graft/LT-Cage – Graft kit, spinal fusion' (the **Device**). The Device was included on the ARTG on 5 August 2005 as ARTG Entry 121164. The sponsor of the registered good was Medtronic, and the manufacturer was identified as Medtronic Sofamor Danek USA Inc, a company based in Tennessee, USA.

6. The Device comprised two separately packaged parts:

   6.1. a metallic spinal fusion cage (**Cage**), and

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6.2. a Kit, which contained: (1) a recombinant human bone morphogenetic protein (rhBMP-2) (**Protein**); (2) a vile of sterile water for injection (**Water**); (3) an absorbable collagen sponge (**Sponge**); (4) empty syringes; and (5) corresponding needles.[1]

7. The intended purpose of the Device (i.e., the two parts together), as reflected in the entry on the ARTG, was for use in spinal fusion procedures in skeletally mature patients with degenerative disc disease (**DDD**) at one level from L4 to S1.[2] The Cage was intended to hold the spine in the desired position; the Protein was the pharmacological active ingredient intended to promote bone growth; and the Sponge was an excipient ingredient intended to act as a carrier scaffold for the Protein to grow new bone before being absorbed into the Sponge.

8. The Device was included on the ARTG as a 'medical device' within the meaning of s 41BD of the Act. The entry on the ARTG identified it as a 'Class III' medical device within the meaning of Pt 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) (the **Device Regulations**).

The supply of the Kit was unlawful

9. As the Kit was not registered, it was not permitted to be supplied, other than as a component of the Device, i.e., in conjunction with the Cage. Section 19D(1) of the Act prohibits, relevantly, the supply in Australia of therapeutic goods for use in humans, unless the goods are registered goods or listed goods, or are otherwise subject to a relevant exemption, approval or authority. There was no relevant exemption, approval or authority in force in the Relevant Period in respect of the Kit.

10. If Medtronic had applied to register the Kit as a therapeutic good on the ARTG, the Secretary would have been required to evaluate the Kit (as a standalone therapeutic good, i.e., other than as a component of the Device) having regard to the criteria in s 25(1) of the Act. As Medtronic did not make any such application, that evaluation did not occur.

11. By supplying the Kit for use in humans other than in conjunction with the Cage, Medtronic contravened s 19D(1) of the Act. The Kit was regulated by s 19D(1) of the Act because it was a therapeutic good that was not a medical device: see s 15A(1). The Protein was a 'medicine' within the meaning of that term as defined in s 3(1) of the Act. By operation of s 41BD(3) of the Act and paragraph 3(c) of the Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2010 (Cth), each of the remaining four constituent components of the Kit were not medical devices. The Kit and its packaging were a composite pack within the meaning of s 7B(2) of the Act.[3]

12. Even if, contrary to the contention in paragraph 11 above, the Kit was at all relevant times a 'medical device', its supply was unlawful by reason of s 41MIB of the Act. Section 41MIB(1) prohibits the supply of a medical device of a kind that is not included

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1 Depending on the size of the Kit, the Kit contained two syringes and two needles, or four syringes and four needles.

2 That is, the fourth lumbar vertebrae to the sacrum.

3 The Kit was not a 'kit' for the purposes of s 7B(1) of the Act.

in the ARTG, unless it is subject to a relevant exemption, approval or authority. There was no relevant exemption, approval or authority in force in the Relevant Period in respect of the Kit.

13. If any of the constituent components of the Kit were (contrary to paragraph 11 above) a medical device, the Kit would have been a 'system or procedure pack' within the meaning of s 41BF(1) of the Act. A 'system or procedure pack' is a medical device, by operation of s 41BF(2) of the Act.

14. The prohibition on supply under s 41MIB(1) is a prohibition on supply of a device not of a kind included in the ARTG. If, for the reason given in paragraph 13 above, and contrary to the contention in paragraph 11 above, the Kit was a medical device, the Kit was not of a kind included in the ARTG (i.e., it was not of the same kind as the Device) within the meaning of s 41BE of the Act.

Medtronic's supply of the Kit not as a component of the Device

15. Between 1 September 2015 and 31 January 2020, Medtronic supplied a total of 16,290 Kits for use in humans not as a component of the Device to the 108 hospitals. This is demonstrated by supply of a Kit other than in conjunction with a Cage.

16. Having decided to withdraw the Cage from the Australian market, from August 2018 to 31 January 2020, Medtronic continued to supply the Kit without the Cage.

C. SUMMARY OF RELIEF SOUGHT FROM THE COURT

17. The Applicant seeks the relief set out in its Originating Application.

D. PRIMARY LEGAL GROUNDS FOR RELIEF SOUGHT

18. As detailed above, on each occasion Medtronic supplied a Kit other than in conjunction with a Cage, it supplied:

    18.1. a therapeutic good which was not a medical device, was not registered on the ARTG, and was not subject to an exemption, approval or authority under the Act, in contravention of s 19D(1) of the Act; or

    18.2. alternatively, a medical device which was not of a kind included in the ARTG, and which was not subject to an exemption, approval or authority under the Act, in contravention of s 41MIB(1) of the Act.

19. Medtronic contravened s 19D(1) (alternatively, s 41MIB(1)) by supplying 16,290 units of the Kit other than in conjunction with the Cage in the Relevant Period. Each contravention attracts a maximum civil penalty of:

    19.1. $9m[4] for any contravention between 1 September 2015 and 30 June 2017; or

    19.2. $10.5m[5] for any contravention between 1 July 2017 and 31 January 2020.

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4 Penalty unit of $180 x 50,000: see s 4AA(1) of the *Crimes Act 1914* (Cth) (**Crimes Act**), as in force at the relevant time.

5 Penalty unit of $210 x 50,000: see s 4AA(1) of the Crimes Act, as in force at the relevant time.

E. ALLEGED HARM

Regulatory objective

20. One of the objects of the Act is to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods (including medicines and medical devices) that are used in Australia: s 4(1). This is effected through a general requirement that therapeutic goods supplied in Australia be entered on the ARTG.

21. The extent and content of the regulatory controls established by the Act depend on whether the therapeutic good in question is a medical device, a biological, or a medicine or other therapeutic good, and the level of risk associated with the therapeutic good in question. Therapeutic goods may only be entered on the ARTG after a pre-market evaluation of the quality, safety and efficacy of the goods for the purposes for which they are to be used. This evaluation is focused on the purpose for which the goods are to be used, as specified in the application for registration, because a good that is safe and effective for one purpose may present significant safety risks, or be ineffective, when used for a different purpose.

Process of evaluation

22. The Kit contained a medicine which was a prescription medicine, and therefore considered to be a relatively high risk therapeutic good. Before it was supplied not as a component of the Device, Medtronic should have applied under s 23 of the Act for registration of the Kit (namely, the medicine and other therapeutic goods within it) on the ARTG. The Secretary would have been required to evaluate whether its quality, safety and efficacy for the purposes for which it was to be used had been satisfactorily established: s 25(1) of the Act.

23. These criteria ensure that all therapeutic goods registered on the ARTG are safe and efficacious for the purposes for which they are to be used, particularly having regard to the relatively high level of risk associated with prescription medicines.

Evaluation processes not followed

24. In the absence of Medtronic applying to the Secretary for registration of the Kit, the Secretary did not have the opportunity to evaluate whether the quality, safety and efficacy of the Kit had been satisfactorily established for use other than in conjunction with the Cage.

25. As part of that evaluation, applicants are required to submit detailed information, including pharmaco-toxicological data; data from clinical trials relating to the proposed indications for the medicine (i.e. the particular condition that it is intended to treat, prevent or diagnose); and any reports of adverse reactions. Specifically, the applicant is required to provide analysis of the efficacy of the medicine for each proposed indication, including why and how the data supports each proposed indication; as well as clinical data pertinent to the efficacy of the medicine in its intended population, including analysis of the risks concerning efficacy and safety in specific sub-populations, e.g. children.

26. Within the Relevant Period, Medtronic supplied units of the Kit which were used in a variety of procedures that were not procedures that could have been performed using the Kit in conjunction with the Cage. For example, the Kit was used in procedures done to the clavicle, hand, scapula, arm, knee, leg, foot and dental/jaw. The Kit was also used in procedures done to specific sub-categories of patients (e.g. children).

27. The Secretary had not evaluated the efficacy or safety of the Kit with respect to these uses. The Secretary was therefore not able to perform an analysis of the risk of adverse events associated with using the Kit in this way or to analyse whether the Kit in these applications would achieve the specified purpose.

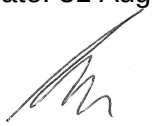
28. It would have been lawful for Medtronic to supply the Kit alone without including it on the ARTG if doctors had applied, and been granted, approval under Special Access Scheme B (**SAS B**) pursuant to s 19 of the Act. SAS B allows doctors to apply to the TGA for approval to use, in a specific patient, a product that is not on the ARTG. If an approval had been granted, Medtronic would have been required to supply the goods in accordance with the approval: *Therapeutic Goods Regulations 1990* (Cth), sch 5A, item 1. A condition of an approval under SAS B is that the doctor ensures the patient provides informed consent to the use of a product that has not been properly evaluated and approved. At no time during the Relevant Period did the Secretary approve the supply of the Kit to specific patients through the SAS B process. That process ensures that doctors are informed as to, and patients are given an opportunity to decide whether to accept, the risks associated with the use of the Kit alone. That process was not followed. In any circumstances, the Kit alone was not subject to any pre-market evaluation.

29. By unlawfully supplying the Kit contrary to s 19D (or in the alternative s 41MIB), Medtronic exposed thousands of patients to procedures that involved administering a medicine for uses in respect of which the Kit had not been evaluated by the Secretary. Medtronic profited from the supply of thousands of units of the Kit in circumstances where the safety and efficacy of the Kit had not been established by the Secretary. In the absence of that evaluation, Medtronic put the health and safety of patients at risk, and undermined the integrity of the regulation of therapeutic goods in Australia.

CERTIFICATE OF LAWYER

I, Sonja Marsic, certify to the Court that, in relation to the concise statement filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 31 August 2021



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