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8 July 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202205484

Dear s 9(2)(a)

**Response to your request for official information**

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 19 April 2022 for information relating to Johnson & Johnson Gynaecare surgical mesh device. I will respond to each part of your request below.

Medsafe is a business unit within the Ministry and is the authority responsible for the regulation of therapeutic products (medicines and medical devices) in New Zealand. The requests are for information from the Ministry of Health and Medsafe, but in the instances where the information requested relates to information associated with regulatory function, Medsafe is referenced in the response.

You asked for:

> *"documents such as emails, reports and internal communication between the Ministry of health, Johnson & Johnson and Medsafe pertaining to the initial safety approval for the Johnson & Johnson Gynaecare TVT model 810081 prior to its introduction into the Public Health Sector*

There is currently no legislative provision for any pre-market assessment or approval process for medical devices in New Zealand. Therefore, this device was not assessed and approved before it was supplied in New Zealand. This part of your request is refused under section 18(e) of the Act as the information requested does not exist.

> *I require non publicly reported documents, emails, reports and internal communication specifically for the Johnson & Johnson Gynaecare TVT model 81008 that was specifically reporting on adverse reactions/injuries [caused by the use of this model] that was being reported to the Ministry of Health from Accident Compensation Corporation [ACC], Medsafe, private medical consultants and DHB's that has not already been published in reports available for the public viewing from when the material was first introduced to the Public Health Sector [Approximately 2006-07??];*

Adverse event reporting relating to the use or implantation of medical devices is not mandated in New Zealand. However, Medsafe receives reports from healthcare professionals, suppliers, manufacturers and patients. In addition, Medsafe receives some limited information relating to treatment injury claims received by the Accident Compensation Corporation. Treatment injury claims do not necessarily relate to a problem with the medical device. For instance, issues such as post-surgical infection are more likely to be associated with the surgery than a device

implanted as part of the surgery. However, where the surgery includes implantation of a surgical mesh device, these reports are included in the Medsafe surgical mesh reporting data to ensure that it is a comprehensive record. In many instances the brand and/or model of device is not specified in the reports Medsafe receives, or it is reported as unknown.

A summary of all information received by Medsafe relating to adverse events associated with the implantation of surgical mesh is published on the Medsafe website. www.medsafe.govt.nz/devices/Surgical%20Mesh/AdverseEventReportOctober2019.pdf

The *Medsafe surgical mesh implant events report* was originally published on the Medsafe website in 2013. This included summary information on adverse events reported to Medsafe. Version 9 of this report that was published in September 2017 was the last version to include report summaries that specified the specific mesh implanted, where this information was known. www.medsafe.govt.nz/hot/alerts/Surgical_Mesh_Implants_September_2017.pdf Later versions did not include this information as the number of reports received did not make this practical and, in a number of instances, the information supplied with the adverse event report, was minimal.

The original *Surgical Mesh for Uro-Genital Report Adverse Event Report* published on the Medsafe website in November 2008 also includes reference to adverse event reports including some associated with Gynaecare TVT. This is available from www.medsafe.govt.nz/Consumers/devices/UrogynaecologicalSurgicalMeshMedsafeReport2008.pdf

An electronic search of the Medsafe records has not provided any further information to that provided above and a manual search of archived records would involve too much collation and research. This part of your request is refused under s18(e) and s18(f) of the Act as the information cannot be found electronically and manual searching of archived records would involve too much collation and research.

> *The names of the persons within Medsafe and Ministry of Health that was receiving and managing all reported incidents of surgical mesh-related injuries for the Johnson & Johnson Gynaecare TVT model 810081 reported by ACC, and the correspondence associated with these injuries such as emails, internal reports and documents that include [but not limited to] what action was taken to address the injuries by the Governmental departments/agencies involved from the introduction of this particular model [Approximately 2006-2007??];*

Adverse events reported to Medsafe from medical devices suppliers or manufacturers, healthcare professionals or patients are received into a generic inbox and may be received and acknowledged by one of several Medsafe staff members. Decisions on what action may be needed is made by a group of staff with expertise in the area. The names of current and past Medsafe staff that may have been involved are withheld under section 9(2)(a) of the Act.

> *On 20 March 2014 a private petition was sent to the Health Select Committee by ACC requesting that an independent inquiry be conducted regarding the safety of surgical mesh in New Zealand, I am seeking a copy of that petition and all associated emails, notes, reports and documents between ACC and the Health Select Committee*

The petition you refer to, that was considered by the Health Select Committee, was submitted by Carmel Berry and Charlotte Korte. Both the petition, and the Government's response are publicly available.

- The petition, Petition 2011/102 of Carmel Berry and Charlotte Korte is publicly available from www.parliament.nz/resource/en-NZ/51DBSCH_SCR69220_1/2ebf5e03f6fae9f78e731ff8ebfce8ded2df857f.

- The Government's response to the petition is also publicly available from: www.parliament.nz/resource/en-NZ/51DBHOH_PAP69804_1/497886ae366b3f4bf270de02ad80e037b7c5c2bd.

For information relating to correspondence between the Health Select Committee and the Accident Compensation Corporation (ACC) you may wish to contact them directly. Their contact details are available at: www.acc.co.nz/contact.

> *Medsafe would have received, data collected [database of adverse reactions] and reported on these adverse reactions for the Johnson & Johnson Gynaecare TVT model specifically only for the pelvic organ prolapse and stress incontinence procedures that was raised by DHB's, Private Hospitals and Consultants that I am seeking all reports, emails, notes and documents from when this specific TVT model 810081 was introduced in 2006-2007 to December 2013;*

Some of this information is published in the *Adverse Event Reports Relating to Surgical Mesh Implants Summary of reports received by Medsafe December 2016.* The report includes summary information on adverse event reports received from 2005 to 2016. www.medsafe.govt.nz/hot/alerts/Surgical_Mesh_Implants_December_2016.pdf

Additional information to that published at the link above cannot be made available without substantial collation or research and so this part of your request is refused under section 18(f) of the Act.

> *International correspondence Medsafe and the Minister of Health received re: concerns raised and known issues with surgical mesh devices from 2006 to date;*

A summary is published on the Medsafe website and is available from: www.medsafe.govt.nz/devices/Surgical%20Mesh/Overseas.asp. In most instances the correspondence received would be notification of information published or to be published on the regulator's website. A detailed search to identify any additional information that may not be publicly available would involve too much collation and research and so is refused under section 18(f) of the Act.

> *copy of the initial Contract agreements and all bonus initiatives/perks for the use of Johnson & Johnson Gynaecare TVT model 810081 that also includes by not limited to any amendments to the initial contract that Medsafe and / or Ministry of Health signed;*

Medsafe is not involved in contracting with suppliers to supply medical devices. Since 2004 it has been a regulatory requirement for suppliers of medical devices (with some specified exceptions) to notify information on the device(s) to a database held by Medsafe. As previously stated, there is no approval process for medical devices prior to supply in New Zealand.

Some information may be held by the DHB's and this could be separately requested. Please note that private hospitals are also involved in the use of surgical mesh.

This part of your request is refused under section 18(e) of the Act as this information is not held by Medsafe or the Ministry.

> *Prior to the introduction of the Johnson & Johnson Gynaecare TVT model into the Public Health Sector in 2006-2007, and BEFORE the Contract was signed off between Johnson & Johnson and Medsafe/Ministry of health, I require the correspondence such as emails, letters, notes, internal phone call records, reports and the like, that specifically outlined any known adverse reactions, faulty products, and / or recalls specifically for the Gynaecare*

*TVT model 810081 that Johnson & Johnson would have advised/outline Medsafe and Ministry of Health;*

There is no pre-market assessment or approval of medical devices in New Zealand and so there is no documentation or information on 'approval' of this device. Medsafe does not advise or approve which devices may be used in the public or private health sector, nor is it involved in contracts regarding the use of medical devices.

Medsafe first became aware of adverse events associated with uro-gynaecological surgical mesh following reports of treatment injury claims received by ACC. This awareness resulted in the preparation of the *Medsafe Surgical Mesh Report – 2008* published on the Medsafe website.www.medsafe.govt.nz/Consumers/devices/UrogynaecologicalSurgicalMeshMedsafeReport2008.pdf . Therefore, this part of your request is refused under s18(e) as this information does not exist.

*From January 2005 to May 2013, how many concerns did Medsafe receive in regards to surgical mesh implants and from which sources were these complaints provided to Medsafe? I require the total amount of reported concerns that Medsafe received specifically for the Gynaecare TVT model 8110081 from the initial introduction into the Public Health sector approximately 2006-2007 to May 2013 only;*

This information is published in the *Medsafe surgical mesh implant events report* published on the Medsafe website. It also includes information on the source of the reports and what brand and model was implanted when this information has been supplied.
www.medsafe.govt.nz/hot/alerts/Surgical_Mesh_Implants_December_2016.pdf

*In 2004 when the introduction of non-absorbable synthetic meshes began1 what protocol was in use for both the Ministry of Health and Medsafe, was this material experimental and if so, for how long were the experimental being trialled? this one is self explanatory, what protocols did the Ministry of Health and Medsafe put into place for the reporting on the use and any adverse reactions/deaths when the initial introduction of non-absorbable synthetic meshes began? As the introduction of non-absorbable synthetic meshes was developed in 2004 and then made available in 2005 in which the New Zealand ministry of Health introduced it to the New Zealand population, was it considered experimental due to its unknown factors of adverse reactions [one year is not considered long enough for trials], and if so, how long was this experimental material trialled/studied for? In specific I am requiring this information for the Johnson & Johnson Gynaecare TVT model 810081 and the reason the American Medical System – Apogee System with InterPro Model 72404025 was replaced by Johnson & Johnson Gynaecare TVT model 810081*

This information is not held by Medsafe. The district health boards (DHBs) or Ethics Committee may have information on any clinical trials that may have occurred. There is no legislative provision for pre-market assessment or approval of medical devices in New Zealand. Since 2004, there has been a legislative requirement for suppliers of medical devices (with some specified exceptions) to notify medical devices supplied to the New Zealand market to a database held by Medsafe (Web Assisted Notification of Devices). It is important to note that DHBs, private hospitals and healthcare practitioners are free to use whatever medical devices they believe, in their professional opinion, are appropriate for the cases they treat. Neither Medsafe, nor the Ministry of Health, was involved in the introduction of these devices to the market, nor do they mandate what devices should be used. This request is refused under section 18(e) as this information does not exist.

*What guidance did Medsafe receive from MDIRC in relation to surgical mesh for Uro-Genital adverse reactions; In November 2008 Medsafe had written a report called "Surgical Mesh for Uro-Genital Report Adverse Event Reports" due to receiving numerous medical device adverse event reports relating to several brands of surgical mesh implants used for uro-genital repairs; Medsafe seeked MDIRC's guidance on what would be the most appropriate response to these reports; I require a copy of all correspondence by Medsafe to MDIRC's in regards to this specific matter and MDIRC's response;*

The Medical Devices Incident Review Committee (MDIRC), in Australia, was asked to comment on a report prepared by Medsafe staff in 2008 following the receipt of 14 adverse event reports associated with the implantation of uro-gynaecological surgical mesh. MDIRC was an advisory committee to the Therapeutic Goods Administration (TGA) in Australia. The Medsafe report was considered at the 2008/4 meeting on 17 November 2008, and the outcome recorded in the minutes which were provided to Medsafe in confidence. The response from MDIRC is summarised on the Medsafe website www.medsafe.govt.nz/devices/Surgical%20Mesh/ActionsTakenByMedsafe.asp, under the 2008 entry.

The recommendations from this meeting were actioned by Medsafe and a letter was sent to the Chief Executive Officers of both public and private hospitals. This letter outlined the key points from the Medsafe review and supported the guidance on the use of uro-gynaecological surgical mesh provided by RANZCOG. A copy of this letter is published on the Medsafe website. www.medsafe.govt.nz/devices/Surgical%20Mesh/ActionsTakenByMedsafe.asp.

Please note, copies of the MDIRC notes are being withheld under section 6(b)(i) of the Act as its release would prejudice information entrusted to the Government of New Zealand from another Government or agency.

*Copies of the 14 adverse reports from 2006, relating to complications from the use of surgical mesh implants for continence and pelvic repairs from ACC2, and all emails, notes and documents associated with these 14 adverse reports between ACC and Medsafe;*

A summary of these reports is included in *the Surgical Mesh for Uro-Genital Report Adverse Event Reports, November 2008* published on the Medsafe website. These reports have now been archived, and any additional information not published in the document linked would probably be redacted under s9(2)(a). www.medsafe.govt.nz/Consumers/devices/UrogynaecologicalSurgicalMeshMedsafeReport2008.pdf.

Your request for additional information to that published at the link above is refused under section 18(f) of the Act as the information requested cannot be made available without substantial collation or research.

*Copies of all emails, documents and notes from when Medsafe requested information about the complications rates to erosion from Johnson & Johnson Medical Specifically for the Johnson & Johnson Gynaecare TVT model 810081 material prior to July 2013 that Medsafe requested from Johnson & Johnson about the complication rates to erosion prior to June 2013;*

Medsafe did not request this information from Johnson & Johnson Medical. Therefore, this part of your request is refused under section 18(e) of the Act as the information requested does not exist.

*Correspondence that includes, but not limited to, emails, reports, notes, documents, and the like, between Ministry of Health and New Zealand Medical Association in regards to the Johnson & Johnson Medical Gynaecare TVT Device, protocols for doctors to follow in reporting adverse events associated with these devices, perks and bonus incentives for the doctors/consultants performing the surgical procedure and level of experience required for these doctors/consultant; - Self explanatory, what protocols were required by those doctors/specialists/practicing consultants when using the Johnson & Johnson Gynaecare TVT model 810081 that that Ministry of Health had provided to either the doctors directly or through the New Zealand Medical Association when reporting adverse reactions; Was there perks and / or bonus incentives for the doctors/specialists/practicing consultants to use this TVT material and what were those perks and / or bonuses?*

Correspondence between Medsafe and the professional colleges is published on the Medsafe website https://www.medsafe.govt.nz/devices/Surgical%20Mesh/ActionsTakenByMedsafe.asp

As previously advised, adverse event reporting is encouraged but not mandated. Any advice to surgeons would have been provided either by the device supplier or by the professional college.

*Copies of all literature that should be provided to patients undergoing surgical mesh implants for continence and pelvic repairs; Ministry of Health provides approval for all literature provided to patients when undergoing surgeries/procedures, I am seeking copies of the literature provided to patients who are specifically undergoing pelvic organ prolapse and stress incontinence procedures and specifically in those procedures will be using the Johnson & Johnson Gynaecare TVT model 810081 prior to July 2013 TVT model 810081 that specifically outline the risks both in the procedure, and the material used;*

Prior to 2013, information about the implantation of uro-gynaecological surgical mesh was provided by the professional associations, and Medsafe recommendations to surgeons using these devices were included in the letters that were sent, and copies are published on the Medsafe website.

More recently, information relating to the use of surgical mesh for urinary incontinence has been developed by representatives on the Mesh Round Table, and is available from www.health.govt.nz/publication/considering-surgical-mesh-treat-stress-urinary-incontinence.

This information is intended to support the informed consent process for anyone considering a procedure involving surgical mesh to treat stress urinary incontinence, but clinicians may use a range of other resources to support a robust informed consent process.

You also requested information relating to contractual perks and bonus incentives

*Insurance policy number [contractual perk or bonus incentives] for CHRIS JAMES acting as Group Manager for medsafe; and – as a public servant, I require the name of the Insurance Company for liability/bond claims for CHRIS JAMES in his capacity as acting as Group Manager for Medsafe that could be worded in his contract such as: contractual perks, bonus incentives, security bonds for any personal liability that is written into his initial contract when he took the role as Group Manager for Medsafe;*

*Insurance policy number [contractual perk or bonus incentives] for ANDREW LITTLE acting as Minister of Health; and – as a public servant, I require the name of the Insurance Company for liability/bond claims for ANDREW LITTLE in his capacity as acting as Minister of Health that could be worded in his contract such as: contractual perks, bonus incentives, security bonds for any personal liability that is written into his initial contract when he took the role as Minister [Hon. Minister, and the like] for New Zealand Ministry of Health;.*

In accordance with section 104 of the Public Service Act 2020, public service employees are immune from liability in civil proceedings for good-faith actions or omissions when carrying out or intending to carry out their responsibilities or when performing or exercising or intending to perform or exercise their functions, duties, or powers. It is not standard practice for the Ministry to take out insurance in respect of individual staff, though some clinical staff may arrange their own insurance practice should they also act as health practitioners (i.e. staff on secondment from a District Health Board).

Ministers may be indemnified against legal proceedings as set out at chapter 4 of the Cabinet Manual, available from: www.dpmc.govt.nz/our-business-units/cabinet-office/supporting-work-cabinet/cabinet-manual/4-ministers-law-and-4 so there is no requirement that they have insurance and in any case, this would not be obtained through the Ministry.

Therefore, this part your request is refused under section 18(e) of the Act as the information requested does not exist.

I trust this information fulfils your request. Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
**Group Manager**
**Medsafe**