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21 September 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022010653

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 Manatū Hauora (Ministry of Health) on 19 August 2022 for information relating to *APO-CANDESARTAN HCTZ 32/12.5, APO-CANDESARTAN HCTZ 32/25, APO-CANDESARTAN HCTZ 16/12.5 - File refs: TT50-11065(a,b).* Medsafe will respond to each part of your request in turn.

The reason(s) for assessing this product under urgency.

This application was processed as a priority assessment as there was a high clinical need to ensure that the New Zealand market had sufficient medicines available for treatment of hypertension. Details of the application are withheld under section 9(2)(b)(ii) of the Act. I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

The reason(s) for assessing this product as suitable for provisional consent.

The criteria for provisional consent are defined in section 23 of the Medicines Act 1981, and described further in Medsafe Guideline on the Regulation of Therapeutic Products in New Zealand, Part 2 at: www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part2.pdf.

This product was approved under section 23 of the Medicines Act due to a shortage of candesartan/hydrochlorothiazide tablets in the New Zealand market. This is reflected in the conditions imposed on the provisional approval of these products, in the gazette notice at the following link: https://gazette.govt.nz/notice/id/2022-go3791.

Any and all correspondence between Medsafe and PHARMAC regarding Candesartan HCTZ between 1st January 2022 and 1st August 2022."

Medsafe has identified the following three documents below within the scope of this part of your request.

- *Medsafe and Pharmac Meeting Notes* dated 3 May 2022
- *Pharmac's Accuretic communications plan* dated 20 June 2022
- *Accuretic and Losartan/HCTZ Email correspondence* dated 9 June 2022

However, these documents are withheld under section 9(2)(b)(ii) of the Act as its release would likely unreasonably prejudice the commercial position of the person who supplied the information.

I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

You may also wish to request any further information from Pharmac at: https://pharmac.govt.nz/news-and-resources/official-information-act/making-an-oia-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