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[redacted]

Response to your request for official information

Thank you for your request for information under the Official Information Act 1982 (the Act) on 2 August 2019 for:

> *"Could you please provide information as to whether we have penicillin/penicillin based products sourced either directly or indirectly from manufacturing plants in India.*
>
> *If so, please can you provide*
> *Manufacturers name*
> *Site of manufacturing*
> *Name of product*
> *Is FDA approval (of the manufacturers site) a requirement for these products to be accepted for use in NZ?"*

Out of 15 medicines with consent to be distributed in New Zealand under the Medicines Act 1981 that contain an active ingredient with "penicillin" in its name (including those that hold an active approval but are listed as not available), seven are manufactured in India. The names of these products, all of which contain the active ingredient phenoxymethylpenicillin, and the details of the manufacturing site registered for all seven of these products are included below.

Product names:

Cilicaine VK 250 capsule 250 mg
Cilicaine VK 500 capsule 500 mg
Arrow – Penicillin V powder for oral solution 125 mg/5 mL
Arrow – Penicillin V powder for oral solution 250 mg/5 mL
m-Penicillin V film coated tablet 250 mg
m-Penicillin V powder for oral solution 125 mg/5 mL
m-Penicillin V powder for oral solution 250 mg/5 mL

Manufacturing site:

Micro Labs Ltd
16 Veerasandra Industrial Area
Anekal Taluk
Kartnataka
Bangalore 056 100
INDIA

Information on the name and location of the manufacturing sites for all medicines approved by Medsafe to be marketed in New Zealand is publicly available. This information can be accessed using the Product Database Search on the Medsafe website at:
https://www.medsafe.govt.nz/regulatory/DbSearch.asp

As prescription medicines, the manufacturing sites for these products must hold valid Good Manufacturing Practice (GMP) certification from the Ministry of Health or a Medsafe-recognised overseas authority in order to be granted consent to be distributed under the Medicines Act 1981. Evidence of GMP compliance issued by the US Food and Drug Administration (FDA) is accepted for this purpose, although evidence issued by other regulators is also recognised by Medsafe. For more information on the Medsafe approval process for medicines and the requirements for the manufacture of medicines, please refer to the Medsafe website and the Guidelines on the Regulation of Therapeutic Products, specifically Parts 2 and 4, accessible at:
https://www.medsafe.govt.nz/regulatory/current-guidelines.asp

Please be aware that Medsafe is responsible for the regulation of medicines in New Zealand and does not manage the procurement or sourcing of medicines. If you would like any further information regarding the procurement of medicines in New Zealand, you should contact the Pharmaceutical Management Agency (PHARMAC).

I trust that this information fulfils your request. You have the right to ask the Ombudsman to review any decisions made under this request.

Please note that this response, with your personal details removed, may be published on the Medsafe website.

Yours sincerely

Chris James
Group Manager
Medsafe