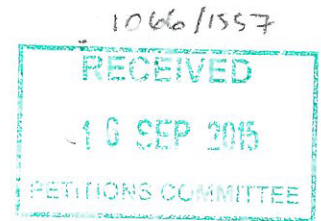




THE HON SUSSAN LEY MP
MINISTER FOR HEALTH
MINISTER FOR SPORT



Ref No: MC15-014855

Dr Dennis Jensen MP
Standing Committee on Petitions
Parliament House
CANBERRA ACT 2600

Dear Dr Jensen

Thank you for your correspondence of 18 August 2015 regarding a petition on warning labels about benign intracranial hypertension for the medicine, Akamin, and all minocycline medicines.

I am advised that benign intracranial hypertension (also known as pseudotumour cerebri) is a known, rare, serious adverse event associated with the use of tetracycline antibiotics, such as minocycline, which is available on the Australian market under the trade names Minomycin and Akamin. Information about this adverse event has been provided in the Product Information (PI) and Consumer Medicine Information (CMI) documents for these products for many years.

PI documents are approved by the Therapeutic Goods Administration (TGA) which is responsible for the regulation of therapeutic goods in Australia. PI documents provide information to guide prescribing, dispensing and administering decisions and assist health professionals to provide patient education for prescription medicines such as minocycline.

The CMI documents, which are required to reflect the information in the PI, contain information to guide consumers on the safe and effective use of the medicine, including advising patients on symptoms they should report to their doctors. The CMI document for Akamin provides the following advice in relation to benign intracranial hypertension:

“If you develop a persistent headache with one or more of the following symptoms - nausea, vomiting, blurred vision or dizziness; see your doctor immediately. These may be signs of a rare condition associated with the use of minocycline called benign intracranial hypertension (increased pressure within the skull).”

The PI and CMI documents are publicly available on the TGA website:
www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=minocycline.

Information from the PI documents is incorporated into the prescribing and dispensing software used by doctors and pharmacists.

The CMI document is made available to consumers either in the product pack or through the dispensing pharmacist.

Information about minocycline for health professionals and consumers is also published on the National Prescribing Service (NPS) website www.nps.org.au.

In December 2013, the TGA published a reminder about the possibility of benign intracranial hypertension associated with minocycline use in the *Medicines Safety Update* (MSU) which was published on the TGA website www.tga.gov.au/publication-issue/medicines-safety-update-volume-4-number-6-december-2013#minocycline and widely distributed to medical practitioners and pharmacists as part of the *Australian Prescriber*.

The TGA keeps the safety of medicines and any necessary risk minimisation actions under regular review. The TGA is currently considering further ways in which to ensure that information about the risk of benign intracranial hypertension with minocycline is brought to the attention of prescribing doctors, dispensing pharmacists and consumers. This will include consideration of possible product labelling options.

I trust this information will assist the Committee in its consideration of the petition.

Yours sincerely

The Hon Sussan Ley MP

6 SEP 2015