Technical Alert

Targeted listing compliance review project: Macular degeneration

As part of the Therapeutic Goods Administration's (TGA) focus to enhance post-market monitoring of listed medicines, a set of future priorities were published on their website, based on data collected from listing compliance reviews and trends.

One of the identified priority areas included listed medicines with eye health indications.
The TGA will, from the 1 July 2017, commence a targeted review in the area of **macular degeneration**.

The review will examine the unauthorised reference of macular degeneration in listed medicines.

As a sponsor, you are encouraged to:

- Ensure your indications are not directly or indirectly referencing macular degeneration
- Re-evaluate the evidence you hold to ensure it supports your indications
- Consider if your product name is potentially misleading within the context of your goods
- You can make changes to the listing of a medicine via the TGA's eBusiness Services.
- If you are unsure if you need to make any changes, you can wait until your medicine is reviewed.
- This targeted project is part of the ongoing post-market review of listed medicines.

For further information, including case examples, refer to the TGA website here:
https://www.tga.gov.au/targeted-project-macular-degeneration#reasons

Pharmacovigilance Inspection Program (PVIP)

As advised in previous newsletters, the Therapeutic Goods Administration (TGA) will be introducing a Pharmacovigilance Inspection Program (PVIP) that will apply to all sponsors of medicines entered in the Australian Register of Therapeutic Goods (ARTG).
The PVIP is expected to be implemented from **1 September 2017**.

The PVIP will assist the TGA to strengthen and broaden its post-market monitoring activities by:

- educating sponsors on their pharmacovigilance requirements
- working with sponsors to ensure pharmacovigilance systems are collecting current information on the safety and efficacy of their medicines
- verifying Australian sponsors' compliance with existing pharmacovigilance requirements.

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What will happen on/from 1 September 2017?

- The TGA will publish on its website, and make available to sponsors, information on the PVIP, including the PVIP Inspection Guidelines.
- The TGA will also hold workshops for sponsors in Sydney, Brisbane, Perth and Melbourne on the PVIP.

When will the inspections commence?

- Inspections will commence after the workshops have been completed and sponsors have received information on PVIP and the revised Pharmacovigilance Guidelines.
- Sponsors will be given 6 to 8 weeks' notice prior to an inspection taking place.

What information will be provided to sponsors on the PVIP?

- Information on the PVIP will be published on the TGA website and distributed to sponsors.
- Sponsors will be provided with PVIP Inspection Guidelines. The guidelines are designed to help sponsors understand the pharmacovigilance inspection program in Australia.
- Sponsors will also be provided with the revised Pharmacovigilance Guidelines.
- Sponsors will have the opportunity to ask questions about the PVIP at the planned workshops.

What timeframe will the TGA provide to the sponsor to prepare for a PV inspection?

- Sponsors will be notified 6 to 8 weeks prior to the inspection.
- The announcement of the inspection will be in writing and may include, for example, the objectives, nature/type of the inspection, the dates and if known the address of the proposed inspection site(s).
- In exceptional circumstances, an inspection may be performed without prior notice.

How often will sponsors be inspected?

- The schedule for Australian pharmacovigilance inspections, including the prioritisation of reinspection will be risk based.
- Early re-inspection may take place where significant non-compliance has been identified.

Is the TGA adopting MHRA style inspections?

- Inspection guidelines drafted are based on the MHRA guidelines, but also address relevant Australian issues and requirements.

What will be published as a result of the PV inspection and how often will they be published?

- The TGA will publish 6-monthly statistics, commencing 12 months after the first inspection, on the number of inspections held, type of inspections, type of findings and whether they have been resolved.
- A summary of conclusions based on this data may be included, particularly in relation to comparisons over time.

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What are the next steps for implementation of the inspection program?

- The TGA has recently circulated the revised Pharmacovigilance Guidelines for sponsor comment; additionally, the PVIP Inspection Guidelines will be circulated for comment prior to finalisation.
- The TGA will advise sponsors once the PVIP Inspection Guidelines and the revised Pharmacovigilance Guidelines have been published on the TGA website.
- The TGA will advise sponsors of the dates for the workshops.

Questions?

If you have any further questions please contact TGA via email: pharmacovigilance.inspections@health.gov.au or telephone (02 6232 8111).

ENDS

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