SAFETY ALERT

DRAP SAFTEY ALERT NO. 47

Safety Alert of Risk of Myasthenia Gravis and Ocular Myasthenia with Statins.

Date: 27th of April, 2024.

Target Audience.

- Manufacturers and Importers of statins;
- Healthcare Professionals; and
- Patients, Consumers or Caregivers.

Background.

The Pharmacovigilance Risk Assessment Committee (PRAC) of EMA in February, 2023 has recommended a change to the product information for statins to include potential risks of myasthenia gravis and ocular myasthenia. In a few cases, statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia. Treatment with statins should be discontinued in case of aggravation of symptoms. Recurrences when the same or a different statin was (re-) administered have been reported.

The MHRA-UK in September 2023 informed the healthcare professional and patient about the European's review recommendation related to new warnings on the risk of new-onset or aggravation of pre-existing myasthenia gravis with multiple statins. The findings of the European review were considered by the Pharmacovigilance Expert Advisory Committee (PEAG) of the Commission on Human Medicines (CHM), which agreed with the recommendations. It was informed that the product information of all statins is being updated to list myasthenia gravis and ocular myasthenia gravis as adverse drug reactions with a frequency 'not known'. New warnings will also be added to the Summaries of Product Characteristics and Patient Information Leaflets.

Action in Pakistan.

The case was discussed in the 4th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) of the DRAP held on 26th of February, 2024 which decided the case as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022, that registration holders of statins (HMG-CoA reductase inhibitors) should update the warning and precaution section about the risk of myasthenia gravis and ocular myasthenia gravis and list as adverse drug reactions with a frequency 'not known' in the adverse drug reaction section.

NPC, DRAP, PM Health Complex, Chak Shahzad Islamabad +92 51 9255981 npc@dra.gov.pk

Therapeutic Goods.

Name: **Statins** are HMG-CoA reductase inhibitors and include atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin and simvastatin. Statins are an acceptably safe and effective group of medicines that help lower the level of low-density lipoprotein (LDL) cholesterol in the blood. Statins play an important role in the treatment of atherosclerotic cardiovascular disease.

Advice for Healthcare Professionals.

Healthcare professionals are advised to refer patients presenting with suspected new-onset myasthenia gravis after starting statin therapy to a neurology specialist – it could be necessary to discontinue statin treatment depending on the assessment of the individual benefits and risks. Likewise, healthcare professionals should advise patients with pre-existing myasthenia gravis to be alert to the aggravation of symptoms while taking a statin.

Advice for Patients.

Patients are informed that many people who take statins do not experience side effects and, where this does happen, these are typically mild – but it is important to read the Patient Information Leaflet that comes with their medicine and talk to a healthcare professional if they are experiencing problems. Patients are also advised not to stop their statin treatment without first discussing this with their doctor. Before taking a statin, inform your doctor if you have a history of myasthenia gravis or ocular myasthenia. Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath. Seek medical help immediately if you develop severe breathing or swallowing problems.

Guidelines for reporting Adverse Drug Reactions (ADRs).

Both healthcare professionals and patients are requested to report any suspected adverse drug reaction (ADRs) with statins medicines to the National Pharmacovigilance Centre (NPC), Drug Regulatory Authority of Pakistan (DRAP) through the Med Vigilance E-Reporting System available on the DRAP website. Similarly, ADRs can also be reported through Med Safety App which is available for download from the App Store (for iOS devices) and Google Play (for Android devices).

References.

- Minutes of the 4th meeting of the Pharmacovigilance Risk Assessment Expert Committee.
- Statins: very infrequent reports of myasthenia gravis report of MHRA-UK.
- Product Information safety updates - October 2023 of TGA- Australia.

NPC, DRAP, PM Health Complex, Chak Shahzad Islamabad +92 51 9255981 npc@dra.gov.pk