SFDA
Safety communication

[07 /12/2022]

Potential Risk of Phospholipidosis Associated with the Use of Hydroxychloroquine

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals (HCPs) about the potential risk of phospholipidosis (PL) associated with the use of hydroxychloroquine.

Hydroxychloroquine is approved by the SFDA for the treatment of rheumatoid arthritis, and systemic lupus erythematosus (Table 1). Drug-induced phospholipidosis (DIPL) is a condition in which drugs cause excessive accumulation of phospholipids in cells. It is characterized by the accumulation of phospholipid–drug complexes as intracellular concentric lamellar bodies that are visible within lysosomes by electron microscopy.

We reviewed the current evidence including published literature and post marketing data to assess the association between potential risk of PL with hydroxychloroquine use. Our review found six published case reports suggesting a possible association between PL with hydroxychloroquine use. In addition, we identified 12 spontaneous case reports of PL with hydroxychloroquine in the World Health Organization (WHO) database. Most cases were females (n=8) and three cases had no documented type of gender. Age was documented in nine cases and found to range from 14 to 36 years. Reaction outcome was reported as recovering in three cases, and unknown in the rest of the cases. The results of Information Component (IC=4.7) revealed a positive statistical association for the drug/ADR combination, meaning “Phospholipidosis” with the use of “Hydroxychloroquine” has been observed more than expected compared to other medications available in the WHO database.

- Therefore, the SFDA requested the marketing authorization holders (MAH) of hydroxychloroquine containing products to update the product information (Summary of Product characteristics (SPC) and patient information leaflet (PIL)) by adding phospholipidosis as following:

Undesirable effects:

Post marketing Experience:

Cases of phospholipidosis have been reported with hydroxychloroquine use during post marketing experience (frequency is unknown).

Table 1. Registered hydroxychloroquine containing products:

Generics Name	Trade Name	Dosage form	MAH
Hydroxychloroquine	Plaquenil®	Tablet	Sanofi
Hydroxychloroquine	Arthosave®	Tablet	Apotex

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Fax: +966-11-205-7662 SFDA

Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa

RMM: