SFDA SAFTEY COMMUNICATION

March 25, 2015

Saudi Food and Drug Authority (SFDA) PRESS RELEASE- Safety Communication About Alzheimer's drug Donepezil (Donecept®) and (Dementile®)

The Saudi Food and Drug Authority (SFDA) would like to notify health care professionals about the recent safety issue of **Donepezil (Donecept®) and (Dementile®)**. New warnings have been added to the prescribing information for the Alzheimer's drug donepezil advising about the risk of two rare but potentially serious conditions: muscle breakdown (rhabdomyolysis) and a neurological disorder called neuroleptic malignant syndrome (NMS).

The Marketing Authorization Holder (MAH) of **Donepezil (Donecept®) and (Dementile®)** has updated the summary of product characteristics (SPC) and patient information leaflet (PIL) of these products to reflect such warnings.

Report Adverse Drug Reactions (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using such a medication and other medications to the SFDA either online, by ordinary mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll Free: 8002490000
Tel: 0112038222 ext. 2356, 2317, 2340
Fax: 0112057662
Email: NPC.Drug@sfda.gov.sa
Website: www.sfda.gov.sa/NPC