# SFDA SAFTEY COMMUNICATION

Apr 18th, 2012

## Saudi Food and Drug Authority (SFDA) PRESS RELEASE – Updates on Safety Information of Dabigatran - (Pradaxa®)

The Saudi Food and Drug Authority (SFDA) would like to share an important safety information with healthcare professionals (HCPs) about increased number of spontaneous reports of fatal cases resulting from bleeding episodes in patients treated with Pradaxa® (dabigatran etexilate).

Since its registration in Saudi Arabia, Pradaxa® is only approved for prevention of Venous Thrombo-Embolism (VTE) in patients following hip or knee replacement surgery. However, **Pradaxa has not been approved, in Saudi Arabia, for the primary prevention of stroke in patients with Non-Valvular Atrial Fibrillation (NVAF).**

Patients with severe renal impairment (i.e. CrCl<30ml/min) must not be prescribed Pradaxa® as it is contraindicated in such a situation. Also, Pradaxa® is contraindicated in patients who are at high risk of bleeding. Therefore, it is highly recommended to monitor patients while on treatment for signs of bleeding or anaemia and to discontinue Pradaxa® when severe bleeding occurs. Thus, the importance of renal function testing needs to be emphasized based on post marketing reports of bleedings and the use of Pradaxa ® in the elderly and patients with high risk of bleeding or patients with severe renal impairment.

Besides the increased risk of fatalities, literature reports showed a higher rate of myocardial infarction among Pradaxa® users compared to other anticoagulants (annual event rate in the RE-LY study: dabigatran 110 mg twice daily 0.82% ; warfrain 0.64%).

The Advisory Committee for Pharmacovigilance at SFDA reviewed the available evidence and recommended the manufacturer of Pradaxa® to update the Patient Information Leaflet (PIL) as well as the Summary of Product Characteristics (SPC) to include new safety information.

In conclusion, physicians who are eligible to prescribe Pradaxa® should keep an eye on the following recommendations:

- **Renal function should be assessed by calculating the creatinine clearance (CrCl) in all patients prior to initiating Pradaxa therapy.**
- **Pradaxa is contraindicated in patients with severe renal impairment (CrCl<30 ml/min).**
- **While on treatment, renal function should be assessed in clinical situations where a decline in renal function is suspected, such as hypovolemia, dehydration, and with certain co-medications, etc.**
- **In elderly patients (>75 years) or in patients with renal impairment the renal function should be assessed at least once a year.**

## Report Adverse Drug Events (ADEs) to SFDA

The SFDA urges healthcare professionals and patients to report ADEs resulted from using such a medication and other medications either online, by regular 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 number: 8002490000
Tel: 012038222 ext. 2317, 2353, 2356, 2340, 5769
Fax: 012057662
Email: NPC.Drug@sfda.gov.sa