Direct Healthcare Professional Communication

Important safety relevant information on Xarelto® (Rivaroxaban): Inclusion of Stevens-Johnson syndrome and agranulocytosis as adverse drug reactions in the product information

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Dear Healthcare Professional,
Bayer Saudi LLC in agreement with the National Pharmacovigilance and Drug Safety Centre, Saudi Food and Drug Authority would like to inform you of the following:

Synopsis

- Stevens-Johnson syndrome (SJS) and Agranulocytosis will soon be included as adverse drug reactions with unknown frequency (post – marketing reports) in the product information for Xarelto®.
- These adverse reactions are very rare, but potentially life-threatening.
- Patients should be informed on potential signs and symptoms and consult their physician, if these would occur.

Background information

Xarelto® is approved for the prevention of thrombosis in patients undergoing major orthopaedic interventions in the lower limbs, for the treatment of deep vein thrombosis and pulmonary embolism and the prevention of recurrent deep vein thrombosis and pulmonary embolism, for the prevention of stroke and systemic embolisms in patients with non-valvular atrial fibrillation.

In the completed clinical trials with more than 40,000 patients exposed to Xarelto® (rivaroxaban), no cases of "Stevens-Johnson syndrome" or "Agranulocytosis" have been reported. In contrast to clinical studies, where suspected adverse drug reactions are captured systematically, for spontaneous reports it is not always possible to reliably estimate their frequency. Taking into account all indications and dosages, and respective sales data, since market introduction of Xarelto ® the cumulative worldwide reporting rate of cases with "Stevens-Johnson syndrome" (SJS) is estimated at 0.04 per 10,000 patient-years (PY) and for "Agranulocytosis" at 0.03 per 10,000 PY (status 15-Sep-2015), respectively. Upon Swissmedic advice, the product information for Xarelto® will be amended to include "Stevens-Johnson syndrome" and "Agranulocytosis" as adverse drug reactions with unknown frequency (Post-marketing reports). The respective latest valid product information is published on www.swissmedicinfo.ch.

The information in this letter has been approved by the Saudi Food and Drug Authority.

Reporting adverse drug reactions

Healthcare professionals should report any suspected adverse reactions associated with use of Xarelto in accordance with the national requirements via the national spontaneous reporting system, to:

National Pharmacovigilance and Drug Safety Centre
Toll free: 8002490000
Fax: +9661 1 2057662
E-Mail: npc.drug@sfda.gov.sa
Online: http://ade.sfda.gov.sa/

Or

Pharmacovigilance department in Bayer Saudi LLC:
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If you have any questions, or if you require any further information, please contact the medical information service of
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With kind regards,

A. Rahman
19-3-2017

Abdulrahman Mohammed Harthi

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