Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No....75..... dated 31/03/20 regarding European Medicines Agency's notification that no change is needed in use of direct oral anticoagulants.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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Circular No. 75 / 2020

06 -08-1441 H

31 -03-2020

No change is needed in use of direct oral anticoagulants following EMA-funded study

The European Medicines Agency has recently issued a notification stating that no change to the conditions of use of the direct oral anticoagulants Eliquis (apixaban), Pradaxa (dabigatran etexilate) and Xarelto (rivaroxaban) is needed following a review of the results of a European study of real-world data for these medicines.

The study, commissioned by EMA and using real-world data from Denmark, France, Germany, Spain, the Netherlands and the United Kingdom, assessed the risk of serious bleeding with these three medicines when used to prevent blood clotting in patients with non-valvular atrial fibrillation (irregular rapid contractions of the heart) and compared this with other oral anticoagulants called vitamin K antagonists.

The results were reviewed by EMA's human medicines committee (CHMP), in consultation with EMA's safety committee (PRAC), and were compared with data from other similar studies and in the published literature. EMA's review concluded that the pattern of serious bleeding seen in patients taking Eliquis, Pradaxa and Xarelto was similar to that seen in the clinical trials on which the authorisation of the medicines were based. The data were not sufficient to allow robust conclusions to be drawn on comparisons between the three medicines.

The study also looked at whether the use of the medicines in clinical practice was in line with the authorised uses and took into account existing contraindications, warnings and advice on interactions with other medicines. EMA concluded that no changes to the product information were warranted, as the data did not provide robust evidence of a high level of non-adherence to the authorised product information.

The study results provided further data on the known increased risk of bleeding in older patients (>75 years). The companies marketing these direct oral anticoagulant medicines will be asked to further explore the issue and to investigate whether changes to the recommended doses could be beneficial for these patients.

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dg-padc@moh.gov.om : البريد الإلكتروني ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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Information for healthcare professionals

- A retrospective, non-interventional study using European databases was carried out in 6 countries to assess the risk of major bleeding associated with use of direct oral anticoagulants (DOACs) when compared to vitamin K antagonists (VKAs), in patients with non-valvular atrial fibrillation. The study had been proposed following a workshop held by EMA in 2015 on the clinical use of DOACs.
- Overall, the new data confirm the bleeding patterns of DOACs versus VKA already observed in clinical trials and described in the product information of the medicines. The benefit-risk balance remains positive for all three DOACs investigated (apixaban, dabigatran, rivaroxaban) within the authorised indications. Comparable results were found in similar studies conducted in Canada and the US.
- There was an observation of increased risk of bleeding in older patients (>75 years). Further studies are needed to explore the issue and to determine whether there are differences in risk between individual DOACs. The data were not sufficient to recommend dosage changes in this population. The companies marketing these medicines will be asked to explore the issue and to carry out an analysis to determine whether modification of the dosing recommendations could be beneficial for older patients.

The direct oral anticoagulants Eliquis (apixaban), Pradaxa (dabigatran etexilate) and Xarelto (rivaroxaban) are taken by mouth to prevent blood clotting in a number of situations, including in patients with non-valvular atrial fibrillation. They are also used to treat deep vein thrombosis (a blood clot in a deep vein, usually in the leg) and pulmonary embolism (a clot in a blood vessel supplying the lungs), and to prevent these conditions from reoccurring. These medicines work by directly blocking a single blood clotting factor in the body; this is why they are called 'direct anticoagulants' as opposed to other anticoagulants such as warfarin that indirectly target various clotting factors.

The above three medicines are available in Oman.

Healthcare professionals are encouraged to report any adverse events suspected to be associated with the above product or any other medicinal product to the Department of Pharmacovigilance & Drug Information in DGPA&DC.

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

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