19 July 2017

Lenalidomide (Revlimid®): Notification about eRMP - Risk Management Plan Website availability

Dear Doctor,

Biologix in collaboration with Celgene would like to inform you of the following in relation to eRMP-Saudi Arabia:

. Celgene has created a risk management plan website (eRMP-saudiarabia.celgene.com) that has been approved by the Saudi FDA.

. The eRMP is an electronic tool that is now available for all Health Care Professionals (HCPs) prescribing Revlimid in order to have access to all material of the Revlimid risk minimization program (i-SECURE)

. All i-SECURE related information will be available in the resources section on the website platform

. All HCPs (treating physicians & dispensing pharmacists) will be registered in the eRMP website through Biologix medical team in Saudi Arabia in order to gain access to the platform

. After registration, HCPs will have access to all i-SECURE RMP files including i-SECURE forms, patient brochures and pregnancy capture forms

. Biologix representative will guide you through the registration process via face to face meeting and provide you with the user guide

. Link to application URL: https://ermp-saudiarabia.celgene.com

Further information on eRMP website:

REVLIMID® (lenalidomide) in combination with dexamethasone (dex) is indicated for the treatment of patients with multiple myeloma (MM)

REVLIMID is indicated in combination with dexamethasone for the treatment of patients with multiple myeloma who have received at least one previous drug treatment.

REVLIMID is indicated for the treatment of patients with anaemia requiring transfusions resulting from myelodysplastic syndrome with low or intermediate risk 1 associated with a deletion 5q cytogenetic abnormality with or without other cytogenetic abnormalities.

REVLIMID® is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib

Lenalidomide, an Imid as thalidomide, caused limb abnormalities in a developmental monkey study. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. Consequently, REVLIMID can cause fetal harm when administered to a pregnant female and is contraindicated in females who are pregnant

REVLIMID is only available through i-SECURE® program which helps to make safe Revlimid prescription and usage.

If you require further information about eRMP-Saudi Arabia, have further questions or need to get access to the eRMP, please contact Biologix medical team at Salehyia Establishment (P.O. Box: 991 Riyadh 11421 KSA) via Phone +966 11 4646955, Fax +966 11 4634362 or email:

pharmacovigilance@blgx.net

MSL Riyadh:	Mohamed Al Ghandour maelghandour@blgx.net	Phone +966 567740805
MSL Jeddah:	Ahmed Tahoun aytahoun@blgx.net	Phone +966 544780886
Senior MSL Riyadh:	Mohamed El Hendawy mahendawy@blgx.net	Phone +966 541929641

Sincerely yours,

Paula Hayek	Tracy Hernandez
Medical affairs lead	Senior Director, Global Risk Management Operations
Biologix Fzco	Celgene