Update to EMA's review of direct-acting antivirals for hepatitis C
Scope of review extended to include the risk of liver cancer

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Information on Direct-Acting Antivirals for hepatitis C

- Direct-acting antivirals work by blocking the action of proteins in the hepatitis C virus which are essential for replication (making new viruses).

For a complete table of authorised products please refer to Safety Circular P09/2016

Information about EMAs ongoing review extended to also assess the risk of liver cancer

In March 2016 the Medicines Authority issued Safety Circular P09/2016, to make aware that the European Medicines Agency (EMA) had started a review of Direct-Acting Antivirals for hepatitis C. This followed reports of hepatitis B re-activation in hepatitis B and C co-infected patients who were treated with direct-acting antivirals for hepatitis C. On 14 April 2016 the scope of this review was extended to include the risk of liver cancer, in addition to the potential risk of hepatitis B re-activation.

This follows emergent study data from April 2016, regarding the risk of liver cancer (hepatocellular carcinoma) coming back in patients who were treated with direct-acting antivirals for hepatitis C. The study suggested that these patients were at risk of their cancer coming back earlier than patients with hepatitis C who were not treated with direct-acting antivirals.

While the review is ongoing, patients should speak to their doctor or pharmacist if they have any questions or concerns. For more information readers are encouraged to refer to Safety Circular P09/2016 and the EMA press release.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on direct acting antiviral drugs. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

Healthcare professionals and patients are encouraged to regularly check the Medicine Authority website for product safety updates as these are issued on an ongoing basis.

The Medicines Authority thanks you for your time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. Your feedback may be returned by folding this page address side up, stapling the ends and then posting (no stamp required)

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Pharmacovigilance Section

Post-licensing Directorate

Medicines Authority

203, Level 3

Rue D'Argens

Gzira GZR 1368