EMA reviews direct-acting antivirals for hepatitis C

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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).

The following direct-acting antivirals have been approved in the EU for treating chronic hepatitis C and are authorised in Malta via centralised procedure:

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number(s)	MAH/license holder
Daclatasvir	Daklinza	Film-coated tablet	POM	EU/1/14/939/001-004	Bristol-Myers Squibb Pharma EEIG
Dasabuvir	Exviera	Film-coated tablet	POM	EU/1/14/983/001	AbbVie Ltd
Sofosbuvir / Ledipasvir	Harvoni	Film-coated tablet	POM	EU/1/14/958/001-002	Gilead Sciences International Ltd
Simeprevir	Olysio	Capsule, hard	POM	EU/1/14/924/001-002	Janssen-Cilag International N.V.
Sofosbuvir	Sovaldi	Film-coated tablet	POM	EU/1/13/894/001-002	Gilead Sciences International Ltd
Ombitasvir / Paritaprevir / Ritonavir	Viekirax	Film-coated tablet	POM	EU/1/14/982/001	AbbVie Ltd

Information about EMAs review to investigate possible hepatitis B re-activation with direct-acting antivirals

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The European Medicines Agency (EMA) has started a review of direct-acting antivirals used for treating chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus).

- Direct-acting antivirals (Daklinza, Exviera, Harvoni, Olysio, Sovaldi and Viekirax) are important medicines for the treatment of chronic hepatitis C and can be used without interferons, which are less well tolerated.
- Until recently, interferons were part of treatment regimens for hepatitis C. Interferons are known to act against both hepatitis B and C viruses, which may be present at the same time in some patients.
- The review follows cases of hepatitis B re-activation in patients who have been infected with hepatitis B and C viruses, and who were treated with direct-acting antivirals for hepatitis C.
- EMA will now assess the extent of hepatitis B re-activation in patients treated with direct-acting antivirals for hepatitis C and evaluate whether any measures are needed to optimise the treatment.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. While the review is ongoing, patients should speak to their doctor or pharmacist if they have any questions or concerns.

More information on these medicines can be found on EMA's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports

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.