

[Drug Injury Watch: Harvoni / Sovaldi Risks: Liver Cancer Return, Hepatitis B Reactivation](#)

(Posted by Tom Lamb at www.DrugInjuryWatch.com on April 23, 2016)

From this April 15, 2016 European Medicines Agency (EMA) News item, "Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 11-14 April 2016" we get an overview of a new drug safety issue involving the direct-acting antivirals class of drugs used for treating long-term, or chronic, hepatitis C:

At its previous meeting in March, the Committee had initiated a review following 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.

In April 2016, data from a study became available regarding the risk of liver cancer (hepatocellular carcinoma) coming back in patients who were treated with these medicines. 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. The scope of the ongoing review has therefore been extended to also assess the risk of liver cancer with these medicines.

As for what this development means for US patients and physicians, Harvoni, Sovaldi, Daklinza, and Olysio are the implicated direct-acting antivirals currently approved by the FDA.

In addition, Viekira Pak (dasabuvir and ombitasvir and paritaprevir and ritonavir) -- which is available for use here -- seems to be a "combination-product" of the Exviera and Viekirax drugs which are listed in the EMA press release, above.

We have written in the past about Viekira Pak side effects in this October 2015 article, "Hepatitis C Drugs Viekira Pak And Technivie Require Warnings Label Changes Due To Liver Injury Reports".

The current EMA Timetable for this PRAC safety review of Harvoni, Sovaldi, and the other new "hep-c" drugs has the current process coming to an end this summer.

Of course, we will be watching for results of safety review and report those out, here, when available.

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Earlier articles by attorney Tom Lamb on the [Side Effects Blog](#):

- [Heartburn Medication Nexium Might Cause Kidney-Related Side Effects](#)
- [FDA Says Onglyza And Nesina Increase Risks of Heart And Renal Failures](#)
- [Stroke, DVT, Pulmonary Embolism, And Kidney Damage Linked To Invokana](#)
- [When Used By Type 1 Diabetes Patients, Invokana Can Cause Ketoacidosis](#)
- [Melanoma Skin Cancer Side Effect Linked To Viagra / Cialis / Levitra](#)

Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
<http://www.DrugInjuryWatch.com>