Dear Editor,

After having read the interesting original document recently published in The Spanish Journal of Gastroenterology “Hepatotoxicity associated with statin use: Analysis of the cases included in the Spanish Hepatotoxicity Registry” (1) we would like to communicate the following clinical case:

A 48-years-old male came to the hospital last April 2013 due to intense asthenia, weight loss and diarrhea. In his medical history, special note was made to his obesity, smoking, moderate alcohol intake, high blood pressure, endogenous depression, dyslipidemia and acute myocardial infarction. His daily treatment consisted of escitalopram 10 mg, alprazolam 0.5 mg three times a day, and since four months ago pitavastatin 2 mg, atenolol 50 mg and aspirin 100 mg once daily. Neither herbal products nor hepatotoxic substances were taken. At the hospital admission, his vital signs and physical examination were normal. The complete blood count, blood clotting and CPK tests were normal. Liver biochemistry showed a cholestatic pattern. A former liver biochemistry made four months earlier was also normal. The complete blood count, blood clotting and CPK tests were normal. Liver biochemistry showed a cholestatic pattern. A former liver biochemistry made four months earlier was also normal. Autoimmunity tests (autoantibodies and immunoglobulin values) and serology tests for HBV, HCV, EBV and CMV were negative. Stool test, ileocolonoscopy, abdominal ultrasonography and magnetic resonance cholangiography were also normal. Symptoms and liver biochemistry normalized progressively over 6 days after hospital admission. Twenty four hours after discharge, a control blood test showed an increase in ALT, AST and alkaline phosphatase (AF) once he restarted home intake of pitavastatin, which had been interrupted during his hospital admission (Fig. 1). Pitavastatin was finally replaced by simvastatin 20 mg once daily. Since then, the liver biochemistry has shown and maintained normal values.

Pitavastatin was marketed in Spain in 2011, and it is the 8th available statin in tablets of 1, 2 and 4 mg. By August 2012, there was no cases reported to the Spanish Hepatotoxicity Registry probably due to its recently marketing and safety profile (1). In a post-marketing surveillance performed in 20,000 Japanese patients taking 1 or 2 mg of pitavastatin for more than 100 weeks, 10.4% of them had some adverse drug event, only 1% was considered severe and 7% of them discontinued the treatment. The most common biochemistry abnormalities were CPK increase in 7.2% of patients, AST increase in 1.8%, ALT increase in 1.5% and GGT increase in 1% of patients (2). The pitavastatin metabolism, independently of the cytochrome P450, is one of the

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**Fig. 1. Evolution of the biochemistry factors.**
pitavastatin advantages versus other statins, making pitavastatin safer in terms of drug-drug interaction, but this is not unique to pitavastatin (3,4).

Statins are safe and probably more beneficial for patients with liver diseases (5) but a reasonable risk management plan seems to be needed, mainly in the post-marketing period as for any drug. Registries of Adverse Drug or other substances Reactions as far as a regular publication of data are needed for a safe medical practice (1,6).

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References