

2012 French Tax on Medical Devices: To be paid by Distributors instead of Manufacturers

A tax on the sale of medical devices and IVDs was introduced in 2001 by AFSSAPS, the French competent authority. This tax was levied at 0.25% of the annual sales in France made by a manufacturer (irrespective of its registered office's location) and was paid by the manufacturer or its European authorized representative (EAR). Manufacturers had to send a declaration of their annual sales and their tax payments to AFSSAPS before March 31 of each year. Manufacturers with sales less than 763,000 Euros (approximately \$1 million) were tax exempt.

The 2012 law on financing French social security (the Social Security Financing Bill), which was officially published on December 22, 2011 and wanted to reduce the national budget deficit, includes a full revision of the AFSSAPS tax. According to the provisions of the new law, the annual tax is now being levied to help finance social security, instead of AFSSAPS, and shall be paid by the companies that are subject to the value added tax (VAT) and make the first sales in France. The first sale in France means the first sale of a medical device or an IVD occurring after being either manufactured in France or imported into France from abroad. For medical device companies in the United States and non-European Economic Area (EEA) countries, this means their French or European distributors. All concerned distributors will have to send a declaration of their annual sales to AFSSAPS before March 31 of each year.

Medical device manufacturers in the United States and non-EEA countries that sell directly (not through distributors) to French hospitals and other end-users will have to designate a financial representative. This representative shall maintain all financial transactions for the manufacturers, including the margins, and shall send the declarations and the tax payments.

The 2012 Social Security Financing Bill 2012 provides that the failure to send the declaration of annual sales to AFSSAPS is punishable by a fine of 45,000 Euros. The fine for an incomplete or inaccurate statement is set at 25 000 Euros.

While this is apparent good news for U.S. and non-EEA medical device manufacturers and their EARs that will not have to make anymore declarations of sales and payments to AFSSAPS, this is bad news for French and European subsidiaries of U.S. and non-EU manufacturers.

The law published in the French Official Journal has also increased the tax rate from 0.25% to 0.29% of sales. In addition, the exemption to medical device companies with sales of less than 763,000 Euros does not exist anymore

The 0.29% tax rate applies to medical device sales including a distributor's margin, which is much more than the 0.25% tax solely on a manufacturer's sales. With the removal of the tax exemption for companies with sales of less than 763,000 Euros, the Joint Committee of the Deputies and Senate Houses estimated that this tax, which generated 17.7 million Euros in 2011, will reach 25 million Euros in 2012. However, this forecasted amount seems a bit pessimistic!