French Decree Hits Device Makers: Crimson Life Sciences Helps Manufacturers Avoid Cash Penalties

The Associated Press

BOSTON & SAN FRANCISCO--(BUSINESS WIRE)--Oct 3, 2012--Crimson Life Sciences, a division of TransPerfect and the only ISO 13485 and ISO 14971 certified translation provider, has announced new services to help manufacturers cope with French Decree No 2012-743 of May 9, 2012 (full text here). The Decree, prompted by recent healthcare scandals including the PIP breast implant recall, makes medical device advertising to healthcare professionals subject to prior approval and prohibits direct-to-consumer (DTC) advertising. In case of violation, the Decree levies stiff financial penalties – up to $125,000 – for each infraction.

Closed for Business: New Compliance Burden for French Device Sales With a 35-hour workweek, proposed 75% tax on top income earners, and now an onerous new advertising regulation for medical device manufacturers, “the risk we run now is that [France] becomes so business-unfriendly that it becomes unbearable,” explained Henri de Castries, CEO of global financial giant AXA. Despite the lobbying efforts of device manufacturers based in France, the government there recently enacted Decree No 2012-743 of May 9, 2012 that, starting January 1, 2013, will require device makers to: 1. Cease all DTC advertising 2. Require prior approval for advertising materials targeted at healthcare professionals, including those currently on the market 3. Require specific statements on marketing material – existing materials must be updated 4. Invoke penalties of up to $125,000 on non-compliant manufacturers A Cure Worse than the Disease? Driven by the recent PIP breast implant scandal involving thousands of women implanted with substandard silicone, the EU has called for increased regulatory scrutiny. EU health commissioner John Dalli was recently quoted as saying, “Everybody was shocked by the scandal involving fraudulent breast implants which affected tens of thousands of women in Europe and around the world.” This, in turn, has led to calls for a “scrutiny panel” to monitor audit assessments, based on device risk level. In the short term, France has taken immediate measures to control advertising aimed at healthcare professionals—installing a layer of regulatory requirements with dubious benefit for the French public.

Crimson Life Sciences Helps Manufacturers Respond Manufacturers in the U.S. are scrambling to respond to the new French Decree. For many, the large volume of advertising content subject to the new controls is daunting. Even websites and promotional videos are subject to the new law—prompting some manufacturers to block French IP addresses from portions of their website out of fear of non-compliance.

According to Marc Miller, president of Crimson Life Sciences, “A number of our clients are taking emergency measures to prepare their advertising with the

appropriate verbiage for approval, but there will be a significant backlog as the deadline approaches." In response, Crimson has increased and trained resources to help manufacturers prepare the required documentation changes.

Among the nine information points required by Decree No 2012-743 are device class, reimbursement information, and a new "internal reference number" issued by the ANSM, the French equivalent of FDA.

"The new reference number requirement could be especially problematic," notes Miller. "Prior authorization by the ANSM includes review of a hefty product file for each individual advertisement and can take up to two months." With millions of French documents to update and submit in Q4, the device industry can add another urgent item to their compliance "to-do" list.

About Crimson Life Sciences Crimson Life Sciences is a division of TransPerfect Translations International, Inc. and is the only translation practice exclusively devoted to the medical device industry. Crimson is the world's first translation firm certified to both ISO 13485 and ISO 9001 and the only translation firm certified to ISO 14971. Crimson's ISO 14971-certified risk management system is the basis for the world's only translation risk management patent (U. S. Patent No. 8,140,322 B2). TransPerfect, certified to ISO 9001 and EN 15038, is the world's largest privately held language services provider with more than 80 offices worldwide. For more information, visit www.crimsonlanguage.com [1].

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