LUZ

MEDICAL DEVICE TRANSLATION NEWS

Produced by LUZ, Inc. — Translation and Localization Solutions July/August 1999

LUZ, Inc • 202 Potrero Ave San Francisco CA 94103 • Tel: +1.800.589.7090 • Fax: +1.415.241.0504 • www.luz.com

Pros of European Currency Integration Outweigh Cons

Recent decline in euro fails to dampen enthusiasm

By Jeanette Marchant—London, UK

Dubbed the Camembert currency (smelly, soft, and French) in the German popular press, the euro has not been universally welcomed in the 11 European Union countries where the currency will be used, a region known as "euroland." Faith in the European single currency among some European politicians and economists has been shaken by its 10% fall against the U.S. dollar since the euro's inception on January 1, 1999. But the general consensus among medical device executives is that the euro is good for multinational companies doing business in Europe, no matter which side of the Atlantic their parent is based.

"The euro will definitely be a benefit, in terms of the cost of transactions and the cost of doing business," says Michel Darnaud, president of Boston Scientific Europe in Paris.

While the immediate challenge to companies is in handling the euro conversion process, benefits have already been achieved from banking efficiencies. "Already we have been able to close several accounts in lire and deutschmarks and centralize these into a euro account. It is easier to manage one euro account," says Philippe Fumière, finance manager at Guidant's Brussels office.

Companies that manufacture most of their devices in the U.S. are exposed to a higher economic risk when the dollar strengthens against the euro.

The initial costs of adapting accounting and invoicing systems to the euro, and the considerable investment required in information technology, should not be underestimated. But the long-term benefits of dealing with one currency rather than 11 are perceived as outweighing any potential negative effects of price transparency. And for U.S.-owned companies, the euro provides some additional benefits and challenges.

"The conversion of euros to U.S. dollars will not have a big influence in the short term, but it will make our lives easier in the long term," says Fumière. The ability to deal with just one exchange rate will facilitate communication and financial reporting to Guidant's parent company in the U.S. While European companies are used to working in different currencies on a daily basis, U.S. firms are less familiar with the relationship between the U.S. dollar and the perplexing array of different European exchange rates. The euro will simplify the conversion process.

The euro will also facilitate the hedging of economic risk. Prior to the euro, companies had to deal with different options in different currencies to hedge against risk each year. With a universal currency, the liquidity options are higher and the economies of scale resulting from dealing with the euro will enable better hedging strategies, according to Fumière.

"Although the euro will assist in the creation of a more cohesive European medical device industry, it is unlikely to help companies to become more innovative. Innovation will continue to emanate mainly from the U.S."

While the devaluation of the euro against the dollar favors exports from Europe, it has had a negative impact on those U.S. companies that are dependent on sourcing their products from outside Europe. Companies such as Guidant, which manufactures most of its devices in the U.S., are exposed to a higher economic risk when the dollar strengthens against the euro. "The economic risk can only be reduced if production is located in Europe," believes Fumière. This fact was a key factor behind Guidant's decision to open a facility in Ireland, within the eurozone.

More companies may follow suit when deciding where to base new production sites in an attempt to lower their exposure to risk. There is already evidence of the perceived benefits of manufacturing within the eurozone in other industries, such as the automobile sector. Toyota, for instance, has selected France for its new manufacturing plant because of its strategic location. The company has also threatened to leave the U.K. if it remains outside euroland.

The potential benefits of the single currency could be greater for European medical device companies than for U.S. companies, commented one finance director of a U.S. medical device company operating in Europe who preferred not to be named. Whereas European companies have previously had to adapt to individual European markets, the

continues on next page

eurozone presents a larger home market, offering the potential for a better competitive position against U.S. device companies.

"The euro will help European companies become more European," believes Boston Scientific's Arnaud. But he argues that many U.S. companies operating in Europe have a head start in that they have already been treating Europe as if it were one single market. "I am managing my business as a European business. Of course, I am also aware of the local country differences. But it seems that European companies were slower, before the euro became a reality, to really manage their operations on a pan-European basis. They were more stuck in national differences than U.S. companies, which were less sensitive to them. As a consequence, we were much quicker to really leverage the European market, as opposed to approaching Europe as a collection of different markets."

Although the euro will assist in the creation of a more cohesive European medical device industry, it is unlikely to help companies to become more innovative, says Arnaud. Innovation will continue to emanate mainly from the U.S.

The Health Industry Manufacturers Association (HIMA) says it is too early to assess what impact the euro has had on HIMA member companies. But the U.S. trade association hopes that by January 2000 the industry will be able to discuss its experiences gained in the euro's first year at the Global Medical Device Conference, to be held in Mexico in early 2000. As co-host with the Mexican medical device association, CANACINTRA, HIMA plans to include a session on the euro at the global meeting, which will be held in Cancun from January 16 to 18.

Meanwhile, although the single currency removes some of the obstacles to pan-European business, medical device companies are still faced with national differences in language, reimbursement rules, and healthcare systems. There is still a long way to go before the creation of a single European market for medical devices.

€ € €

Euro Milestones

May, 1998: Eurozone created comprising Austria, Belgium, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Portugal, and Spain.

January 1, 1999: Euro became official currency in the 11 member states for paper transactions only; national currencies continue to be used for cash transactions. The exchange rate of the euro against the U.S. dollar started out at $1.1789. As of late July, it was valued at $1.0624, a decline of almost 10%.

January 1, 2002: The euro enters circulation in the eurozone.

June 30, 2002: National currencies of the 11 member countries will cease to be legal tender.

Liability Spotlight: Off-Label Use And Over-Promotion

Two theories frequently advanced by plaintiffs in product liability litigation against manufacturers of medical devices are off-label use and over-promotion.

Off-Label Use: "refers to the use of a drug or device in a manner not approved by the FDA and not set forth in the product's labeling materials." *Washington Legal Foundation v. Kessler*, 880 F. Supp. 26 (D.D.C. 1995).

Over-Promotion: occurs when a manufacturer minimizes or dilutes the warnings which must accompany a drug or device, thereby inducing a physician or other health care provider to prescribe a drug or use a device without due regard for the warnings. It can also mean an over-emphasis on benefits or effectiveness, i.e., a failure to present a balanced view of risks versus benefits.

The following risk management strategies should be considered in order to avoid claims for off-label use and over-promotion:

- Do not market use beyond what is on the labeling.
- If you learn of off-label use, inform the medical community it is not an approved use.
- If off-label use is widespread, consider whether labeling or warnings would be appropriate.
- Monitor increases in sales to determine if due to off-label use.
- Do not make representations regarding efficacy or safety beyond what studies can verify.
- Printed advertisements (calendars, date books, etc...) should include product warnings or at least a reference to see health care provider.
- Do not minimize warnings, no matter how small the risk.
- Be sure the sales force is trained not to over-promote products or to urge off-label use.
- Thoroughly document training of the sales force not to engage in over-promotion or marketing off-label use.
- Consider a comprehensive review of product labeling and marketing materials by in-house or outside counsel.

Source: Steven M. Kohn, Partner, Crosby, Heafey, Roach & May, Oakland, CA, and Michael K. Brown, Partner, Crosby, Heafey, Roach & May, Los Angeles, CA (skohn@chrm.com or mbrown@chrm.com)

About *Medical Device Translation News*

Medical Device Translation News is produced by LUZ, a technical translation company serving the medical device, diagnostic, and pharmaceutical industries since 1994.

To register for a free subscription to Medical Device Translation News, please visit our Web site at www.luz.com. Subscribers can also receive Medical Device Translation News via e-mail in PDF format in lieu of a fax copy. If you are interested in this option, please send an e-mail to newsletter@luz.com and write "e-mail subscription" in the message header.

Editorial Team

Monique Rivas, Brian Casey, Sarah McCabe