Central & Eastern Europe
Commercial Update

A publication of the U.S. Department of Commerce, International Trade Administration, Central and Eastern Europe Business Information Center (CEEBIC), in cooperation with the U.S. Agency for International Development

September/October 2004

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Central and Eastern Europe Commercial Update Announcement

Please be advised that the Central and Eastern Europe Business Information Center's (CEEBIC) publication, the "Central and Eastern Europe Commercial Update" will become the "Southeastern Europe Commercial Quarterly" as of September 30, 2004. CEEBIC will no longer provide publications, business counseling, and information resources on the countries of: Czech Republic. Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, and Slovenia. Companies with questions on exporting and investing in these countries should no longer contact the CEEBIC office. The "Southeastern Europe Commercial Quarterly" will provide similar information on: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Serbia and Montenegro, Macedonia, Kosovo, and Romania.

U.S. companies with inquiries about Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, and Slovenia should visit: *www.mac.gov/ceebic/shutdown.html* to be directed to the appropriate office. U.S. companies with inquiries about exporting to these countries should contact

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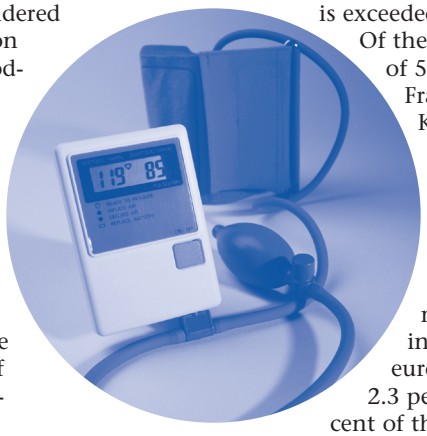
Market Highlight: Medical Devices in an Enlarged European Union

by Kerryn Hannon

Medical devices are part of a fast-changing technology market in which the product life cycle can be as short as 18 months. Products' short life cycles, compounded with international technological advancements, have hindered the effort of the European Union (EU) to standardize medical products. With the newly enlarged 25-member EU, the market faces additional challenges of harmonizing standards and providing effective legislation to ensure the safety, efficacy, and quality of medical devices across the European market. Conversely, the new member states have an incentive to close the gap with the EU in terms of product quality and safety standards.



This article will explain the policies and regulations associated with how medical devices are exported to the EU and how the new member states had to adjust their product manufacturing standards to suit entry into the single European market. Two accession countries, Hungary and the Czech Republic, have emerging markets in medical devices that will potentially provide business opportunities for U.S. firms. To provide U.S. companies with a better understanding of the situation in Eastern Europe, this article will briefly examine changes that have occurred in the health care sectors in Hungary and the Czech Republic. The liberalization of the health care sector and the increased standards for goods traded on the European market are representative of the transformations taking place in many accession countries.

Background Market Information

The European Commission considers medical devices to be those finished products that are used specifically for a medical purpose. According to a 1993 Council of the European Communities Directive, a medical device is any instrument to diagnose, prevent, monitor, treat, or alleviate disease, injury, or handicap, or to address the anatomy or a physiological process. These devices do not include toiletry items, aids for handicapped persons, and software used in combination with non-medical equipment.

The European medical technology market comprises 30 percent of the global market and is exceeded only by the United States. Of the total European market value of 54.8 billion euros, Germany, France, Italy, and the United Kingdom dominate nearly 70 percent of that market. The new EU member states make up 3.5 percent. Of those, Poland, the Czech Republic, and Hungary account for the greatest total expenditures in medical technology, spending 0.77, 0.37, and 0.36 billion euros, respectively, and employing 2.3 percent, 1.3 percent, and 1.2 percent of the total European medical work force, respectively.

Industry analysts believe that nearly 8,000 types of medical devices are sold on the European market. Because of the large quantity of products and their diversity, strong regulations and conformity legislation are needed to ensure consumer safety and more effective market surveillance. Without the implementation of harmonized standards, new member states would encounter greater difficulty in attracting investment to the Eastern European medical devices market. The medical devices industry in the new member states is relatively young and is influenced by a variety of factors, including technological innovations, assorted systems for health care, and the needs of both health care professionals and patients.

Legal Information

Upon creating a single economic market in 1992, the European Union established product standards and regulations for member states engaged in trade. The regulatory technique, called the New Approach to Technical Harmonization and Standardization, established the principles of legislative harmonization, the technical specifications and essential requirements of products, and the application of the standards.

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Eye on Southeast Europe

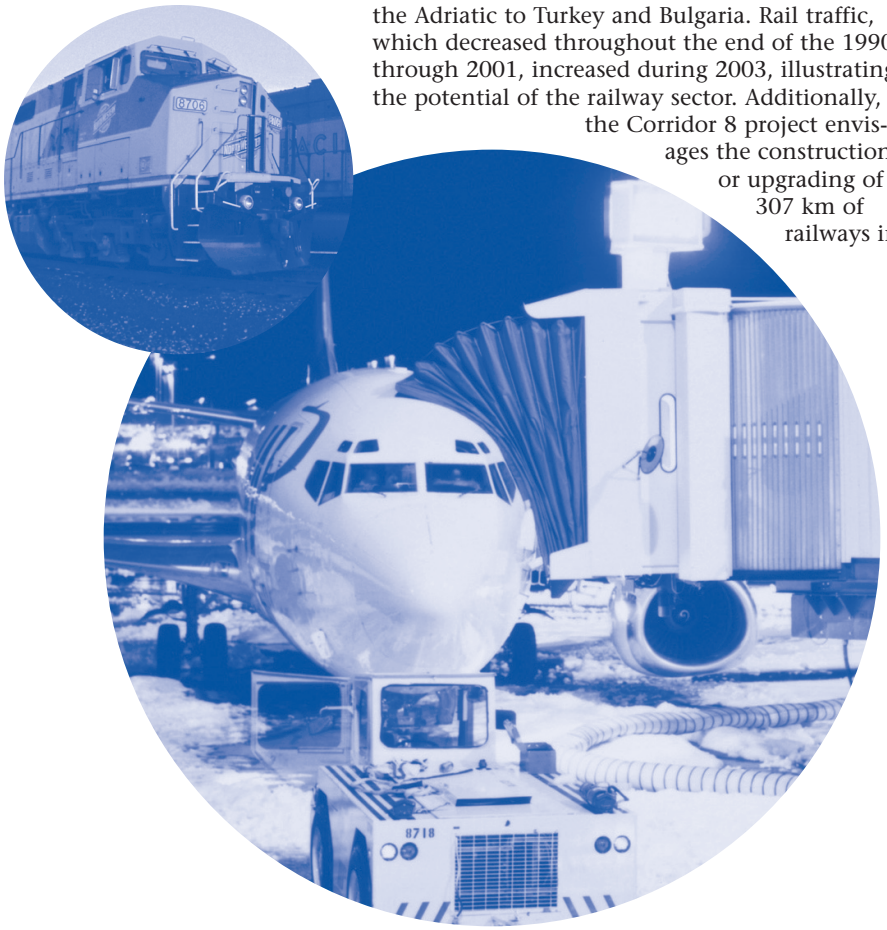
Transportation Infrastructure Development in Southeastern Europe—Part III

by Arben Zajmi

This article—the third and last on transportation infrastructure in Southeastern Europe—gives a more detailed perspective on Macedonia, Romania, and Serbia and Montenegro. Albania, Bosnia and Herzegovina, Bulgaria, Croatia, and Kosovo were the subjects of part two. Part one was a general view on the infrastructure in the region and major projects.

Macedonia

Macedonia is a small country, with a population of 2.1 million and a gross domestic product (GDP) per capita of $1,835. Macedonia maintains adequate north-south road and rail links with Serbia and Montenegro and with Greece but has poor connections with Albania to the west and Bulgaria to the east. As of 2000, Macedonia had 12,522 kilometers (km) of roads, of which 7,246 km were all-weather roads, including 144 km of motorway and 541 km of international class roadways. Macedonia is a transit country for Corridor 8 and is expected to benefit from the construction (under EU auspices) of this east-west network of routes across the Balkans from the Adriatic to Turkey and Bulgaria. Rail traffic, which decreased throughout the end of the 1990s through 2001, increased during 2003, illustrating the potential of the railway sector. Additionally, the Corridor 8 project envisages the construction or upgrading of 307 km of railways in Macedonia (including 80 km toward Bulgaria and 66 km toward Albania), but only 55 percent had been completed by early 2004. Also, the proposed Pan-European Corridor 10 (and 10d) will traverse Macedonia, linking Greek seaports in the south with Central European road and rail networks in the north. Regarding air traffic, the past few years have produced an increase in air transport of goods, to more than 11,282 tons annually. Macedonia has two international airports: one in Ohrid, the other in Skopje. There are two main airlines: Avioimpex and Macedonian Airlines (MAT). MAT has been the national flag carrier since 2000.

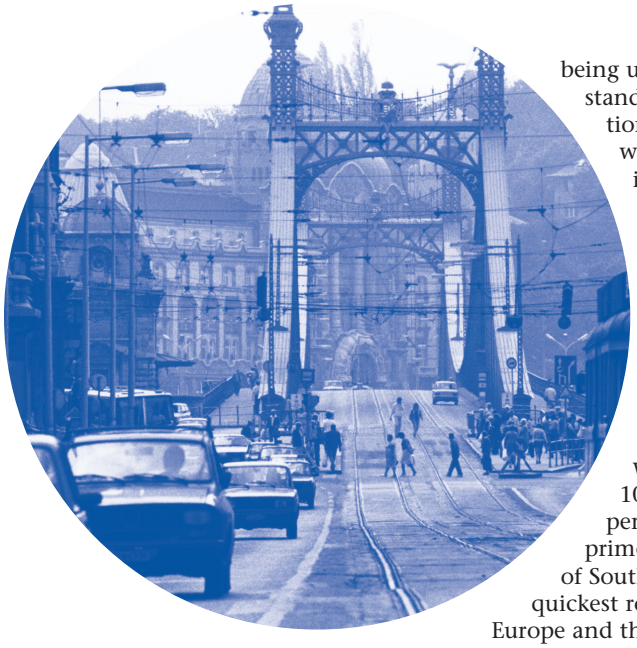


Romania

Romania, with a population of 21.7 million and a GDP per capita of $2,070, is bordered by Ukraine, Moldova, the Black Sea, Bulgaria, and Serbia and Montenegro. It is crossed by three Pan-European corridors: Corridors 4, 7, and 9. Romania's public roads cover 78,000 km and need constant repair. The estimated cost of the proposed national program to construct and upgrade the road infrastructure is $3.1 billion from 2004 to 2007. The rail network—the primary means of internal transport for passengers and freight—covers 14,217 km and is the fourth largest railway network in Europe. However, only 35 percent of the system is electrified. Annual cargo traffic volumes are approximately 70 million tons and are mainly coal, oil products, common metals, cement, quarry products, chemicals, and agricultural products.

European Union assistance to Romania is substantial: $764 million annually from three pre-accession assistance programs. The funding for two of the programs, ISPA and SAPARD, is earmarked for infrastructure spending. Romania also receives sovereign loans from the World Bank, European Investment Bank (EIB), and European Bank for Reconstruction and Development (EBRD) to help upgrade its main road corridors.

Shipping along the Danube, which flows 1,075 km through Romania and provides the country with its principal trade connections to Central Europe, has remained steady over the past few years. The canal from the Black Sea near Constanta to the Danube will eventually offer long-term opportunities for development as the newly independent Caspian states seek outlets for oil and gas exports that bypass the Bosphorus Straits. Romania also has three international and 16 domestic airports. Four new domestic airports are planned, and the one at Cluj-Napoca is



being upgraded to international standards. Bucharest International Airport at Otopeni, which now has an operating capacity of about 3 million passengers and 25,000 tons of cargo per year, is being modernized.

Serbia and Montenegro

Serbia and Montenegro, with a population of 10.7 million and a GDP per capita of $2,166, has a prime location in the middle of Southeastern Europe as the quickest road link between Western Europe and the Middle East. However, Serbia and Montenegro has been unable to capitalize on its geography, and large-scale investment is needed for it to become a regional transportation hub. In 2001, Serbia and Montenegro had almost 45,000 km of roads, of which about 62 percent were modern paved roads. The total road density, 43.9 km per square kilometer of land area, is about average for European countries. The main project to improve the road network is the EU-backed Corridor 10 motorway running from Vienna to Istanbul through Serbia. In 2001, Serbia and Montenegro had 4,058 km of railway track, of which just over one-third was electrified. The modernization of some railway lines is planned to be completed by 2010. The waterway network is concentrated in the north of the country. Of its total length (1,599 km), rivers account for 1,000 km. The remaining 599 km is the Danube-Tisza-Danube (DTD) canal system. Under the Stability Pact for Southeastern Europe, most of the funding has now been raised to reconstruct the Sloboda Bridge over the Danube, but progress in clearing the river has has been slow. Serbia and Montenegro has four civilian airports—Belgrade, Tivat, Podgorica, and Nis—all of which are in need of serious upgrades.

Conclusion

The main objective of this series of articles on transportation infrastructure in Southeastern Europe has been to give an overview of the economic sector, major projects, and development perspectives at the regional and state levels. The information provided is helpful for U.S. companies that are considering the infrastructure capacities of those networks or potential business opportunities in exporting or investment. As the articles have shown, the sector has opportunities in the areas of construction equipment, technology, and advisory services—all products and services in which U.S. companies can offer significant experience and expertise. For more information, please refer to the CEEBIC Web site at *www.mac.doc.gov/ceebic*. For longer versions of the above articles, or for more-detailed research, please consult the following sources of information:

1. Albanian Daily News (*www.albaniannews.com/*)
2. The Economist Intelligence Unit (*www.eiu.com/*)
3. European Commission/Economic Reconstruction and Development in South East Europe (*www.seerecon.org/infrastructure/sectors/transport/documents/REBIS/*)
4. European Bank for Reconstruction and Development (*www.ebrd.com*)
5. European Investment Bank (*www.eib.org*)
6. United Nations Mission in Kosovo (*www.unmikonline.org/*)
7. Trade and Transport Facilitation in Southeast Europe Program (*www.ttfse.org/*)
8. World Bank (*www.worldbank.org/*)

Announcement Continued—*from page 1*

the Commercial Service office in these countries or a local U.S. Export Assistance Center. Contact information for these offices can be found at *www.export.gov/cs*

Past editions of the "Central and Eastern Europe Commercial Update" can be found at: *http://www.mac.doc.gov/ceebic/publications/archive.htm*

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Around the Region

Albania: Seaport Expansion

The port of Durres is Albania's largest seaport. Its operations account for almost 50 percent of Albanian imports and exports. The port is currently undergoing a massive renovation that will increase its capacity and improve the port's operations, efficiency, and revenues. The 3 million euro project will undertake the challenge of reconstructing the seaport by deepening berths at the port's terminals, widening the port entrance, and setting up a new lighting system. The largest portion of the investment will be used to install a suitable drainage structure.
Source: *Southeast European Times*

Bulgaria: Government Plans Major Investments in Energy Sector

Energy Minister Milko Kovachev announced that Bulgaria plans to invest over $7.3 billion in energy investment projects by the time it enters the European Union in 2007. The projects are primarily geared toward increasing energy system efficiency, meeting environment protection regulations, and making technology upgrades in power facilities. Minister Kovachev estimated that approximately 60 percent of the planned investment will be put toward the electricity sector.
Source: *seenews.com*

Romania: Seeking Investment in Energy Sector

According to the Economy and Trade Ministry, Romania needs approximately 1.5 billion euros in investment to meet environmental protection objectives in the energy sector. Air protection objectives include decreasing sulphur and nitrogen oxide emissions and cutting mechanical particle emissions in coal-burning power stations. Water protection measures focus on lowering the pollution concentrate in wastewater and upgrading the technology used in power stations.
Source: *seeurope.net*

Slovakia: FDI and GDP Growth

According to the Slovak Investment and Trade Development Agency, Slovakia attracted $1.3 billion in foreign direct investment (FDI) during the first half of 2004. This figure is almost equal to the total FDI for all of 2003. Most of the growth is attributed to auto parts manufacturing associated with last year's $1.5 billion investment by Korean carmaker Kia. In other news, the World Bank has predicted that Slovakia should experience 4.0 percent growth this year and expects a similar growth rate for 2005.
Source: U.S. Embassy Bratislava and World Bank

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Exporter's Corner

Did you know …

Most frequently exported products from the United States to Central and Eastern Europe in 2003:

Importing Country	Product	Harmonized System Code
Albania	Machinery	84
Bosnia-Herzegovina	Iron and steel products	73
Bulgaria	Machinery	84
Croatia	Electrical machinery	85
Czech Republic	Machinery	84
Estonia	Iron and steel	72
Serbia and Montenegro (including Kosovo)	Machinery	84
FYR Macedonia	Meat	2
Hungary	Aircraft, spacecraft	88
Latvia	Meat	2
Lithuania	Vehicles, not railway	87
Poland	Machinery	84
Romania	Iron and steel, aircraft, spacecraft	88
Slovak Republic	Vehicles, not railway, electrical machinery	85
Slovenia	Machinery	84

(Source: *World Trade Atlas*)

Frequently Asked Questions

Where can I find a list of U.S. firms operating in Central and Eastern Europe?

The American Chambers of Commerce in the region might be a useful source of information. The mission of the AmChams is to be the leading representative for U.S. and international business in its respective country and to promote the global competitiveness of the country. For each AmCham's contact information, go to the CEEBIC Web site at *www.mac.doc.gov/ceebic/*. Select a country page from the column on the left-hand side. In the drop-down menu Country Information, select Useful Resources, then WWW Related Links. You will find a link to that country's AmCham under business contacts. Also under Useful Resources, you can find a list of U.S. companies operating in the country. Finally, to access a directory of U.S. companies operating in foreign countries, please visit *www.uniworldbp.com/*.

How do I find information about a particular overseas company?
Various public and private resources have services designed to help U.S. exporters find information about overseas companies. International Company Profile (ICP) is a program offered by the U.S. Department of Commerce for some countries to portray the reliability of prospective trading partners. Information provided includes type of organization, year established, size, general reputation, territory covered, sales, product lines, principal owners, financial information, and trade references, with recommendations from on-site, U.S. commercial officers as to suitability as a trading partner. The results of your request will take 30 to 45 days and will cost $100 per report. You can place an order for this service through your local Export Assistance Center (EAC), and can locate the nearest EAC on the CEEBIC Web site at *www.mac.doc.gov/eebic/ceebic.html*. Under the drop-down menu Other Resources, select Key Contacts for a list of U.S. Department of Commerce programs.

Medical Devices—*from page 1*

Within EU legislation, medical devices are regulated by three directives:

- Directive 90/385/EEC on Active Implant able Medical Devices (AIMDD 1990),
- Directive 93/42/EEC on Medical Devices (MDD 1992), and
- Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD 1998).

Those directives are based on the principles set forth by the Council of the European Communities in its Council Resolution on a New Approach to Technical Harmonization and Standardization. The council defines the necessary health and safety requirements and the conformity procedures that must be met before products are placed on the market. Requirements address patient safety; chemical, physical, and biological properties; infection; radiation; energy sources; and information to be supplied by the manufacturer. Regulations are limited to "essential" requirements and do not contain specific technical rules, so the directives allow for technological flexibility to encourage innovation in the field. A complete list of the essential requirements may be found in the first annex of Council Directive 93/42/EEC.

The directives state that no product may be placed on the market without having undergone risk assessment and a risk–benefit analysis. The manufacturer is obligated to reduce risks, take adequate protection measures for risks that cannot be avoided or eliminated, and inform users of the risks from shortcomings of the protection measures adopted. Upon registering products to be traded on the medical devices market, producers are obligated to disclose the results of clinical trials in which the medical devices were used.

Except for low-risk devices, conformity assessment procedures involve independent bodies whose purpose is to determine if the essential requirements have been met. The national authorities of each member state have both the responsibility and the discretion to appoint the independent bodies that will determine compliance with conformity requirements. A full list of notified bodies designated by the member countries can be found in the *Official Journal of the European Communities* C 302. A list of contacts within the national competent authorities may be found at the European Commission Web site *www.europa.eu.int/comm/enterprise/medical_devices/ca/list_ca.htm*. In the case of compliance of medical devices, the independent body must be an authorized representative located in Europe.

To ensure that conformity measures are being upheld in the medical devices market, the member countries use market surveillance as the essential enforcement tool. Market surveillance includes checking that products meet requirements, taking action to bring non-compliant products into compliance, and applying sanctions when necessary. Although it does not perform assessment, the European Organization for Conformity Assessment (EOCA) helps both independent bodies and manufacturers to understand conformity procedures and regulations and helps them to establish compliance. The EOCA is an independent and non-profit European body that was established in April 1990 by the European Commission, the European Free Trade Association (EFTA), and the European Standards Bodies. The EC Declaration of Conformity may be found in the second annex of Council Directive 93/42/EEC.

To remain current with the medical devices legislation and decisions made by independent competent authorities, the president of the European Union organizes meetings periodically to discuss overall policy issues. At the July 2004 meeting, the participants discussed the regulatory challenges posed by new technologies, such as robotic surgery and minimally invasive surgery, which have recently been introduced in the market. The challenges faced by the competent authorities include conformity compliance and safety assurance of the new products.

In an effort to help new EU members and future accession countries smooth the transition to European standards, the EU proposed agreements such as the Protocol for European Conformity Assessment (PECA). This mutual recognition agreement establishes acceptance by national authorities of the other countries' notified bodies. Once a medical device is classified, specific compliance regulations are then applied to verify its conformity (classification criteria may be found in the 2nd annex of Council Directive 93/42/EEC). The CE mark (Conformité Européene) denotes the manufacturer's compliance with the necessary health and safety regulations. The manufacturer can sell products within the European marketplace once the products have a CE mark. Each member state is obligated to enforce the European Commission regulations, which ensure that the products placed on the market are safe.

Case Studies: Hungary and the Czech Republic

Hungary and the Czech Republic became members of the European Union on May 1, 2004. In preparation for accession, all of the new member states had to raise their medical standards to conform to European regulations. As in other new member states, the infant medical devices markets in Hungary and the Czech Republic are developing rapidly and are becoming more open to foreign investment.

Hungary

In 1990, Hungary implemented a decentralization reform, which devolved authority from the national government to local and regional

authorities and initiated the creation of semiautonomous health insurance agencies. Agencies within the Ministry of Health, such as the Institute of Surgery, the National Institute of Medicine, and the Institute for Medical and Hospital Engineering, are all semi-independent national bodies that are within the authority of the ministry's National Institutes of Health. The decentralization of the Ministry of Health created incentives for accountability and efficiency. One result of the reform was the establishment of a more comprehensive plan for health care. Currently provided by the single National Health Insurance Fund, this new contribution-based health care system replaced the old tax-based system. The National Health Insurance Fund Administration falls within the national authority of the Ministry of Health, Social, and Family Affairs. The current governance structure in Hungary resembles that of Sweden, Norway, and Denmark, where two tiers of authority exist. The Hungarian government takes direct responsibility for public health services, but the municipalities are responsible for primary health care.

Hungary's $200 million market for medical equipment is dominated by imports, which represent nearly 85 percent of the total market. Of those imports, between 10 and 15 percent are imported from the United States. As with all imports, U.S.-made medical products are marketed through authorized distributors. Because of the high quality of products manufactured in the United States and the increased demand for quality technology, imports from the United States are expected to grow at a rate of 4 to 5 percent over the next five years.

Despite the demand for a wide range of equipment in Hungary, the U.S. Commercial Service has recognized that the best prospects for U.S. exporters include products for cardiovascular and nuclear medicine, diagnostic and surgical equipment, and health care information systems.

Czech Republic

As in Hungary during 1990 and 1991, the Czech government began to liberalize the health care system and to move toward a social insurance model. Reform of the health care system included a change from tax-based financing to health insurance financing and focused on the quality of care provided by medical institutions. During the decentralization, public health responsibilities devolved to local governments, with an increase in the influence of municipalities. Within the authority of the Ministry of Health lie the National Institute of Public Health, the National Health Board, and the Institute of Health Information and Statistics. Primary care providers are nearly 98 percent private, as decentralization provided incentives for independent general practitioners to open private practices.

According to the World Health Organization's Regional Office for Europe, the Czech Republic is one of the healthiest of the Central and Eastern European countries. Because of their successful decentralization and ability to maintain high health standards, the Czech Republic and Slovenia are both ranked as the accession countries with the best health indicators and both approach Western European levels.

More than 65 percent of all medical devices used in the Czech Republic are imported. Imports include, but are not limited to, sterilizing equipment, dental equipment, surgical and dental instruments, and X-ray machines. Of medical device imports, 17 percent originate in the United States. About 40 medium to large companies that produce medical devices represent 35 percent of the Czech Republic's estimated $450 million medical devices market.

According to the U.S. Commercial Service, the best prospects for U.S. exporters include computer-processed visual systems, laser equipment, implants, medicine infusion pumps, X-ray and mammography systems, balneotherapy equipment, endoscopes, and laparoscopes. In addition, the home health care sector is in its infancy, so there is a potential for U.S. firms to capitalize on the export of home health care products and mobility equipment.

Conclusions

Although the European medical devices market is the second largest in the world, it remains a largely unknown and untapped sector. Despite the current trend of Eastern and Central European countries trading within the EU, the United States can enter the market and can increase its market share because of the high quality of U.S. products. As the examples of Hungary and the Czech Republic show, domestic production of medical equipment is low, and the medical devices market is primarily import-driven. U.S. companies have the opportunity to sell devices through domestic distributors and to become stronger in the Eastern European medical devices market. Additional information on the accession countries, plus specific contacts, may be found on the CEEBIC Web site, *www.export.gov/ceebic*.

Sources:

EUCOMED (*www.eucomed.be*)

EU Observer (*www.euobserver.com*)

European Commission (*www.europa.eu.int*)

Medical Devices (*www.europa.eu.int/comm/enterprise/medical_devices/index.htm*)

CE-Mark Online (*www.ce-mark.com/cedoc.html*)

EurActiv Online (*www.euractiv.com*)

CEEBIC Country Commercial Guide

World Health Organization Europe (*www.euro.who.int*)

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