What trends offer opportunities on the European medical devices market?

Many countries in Europe are currently facing financial pressure on their health-care budgets. However, the medical technology sector is not as vulnerable to this recession as other industries and the market still offers a range of opportunities to exporters from developing countries. Opportunities exist for exporters from developing countries who can offer cost-effective, innovative and/or sustainable products.

Growing aged population

With 23% of the population currently aged 60 or older, Europe is home to a relatively aged population. This is a result of the higher life expectancy and decreased birth and mortality rates. By 2030, more than 25% of the population in Europe will be 60 or older. The growing senior population is an important growth driver for health care. According to Johnson & Johnson, “people over the age of 65 years use approximately seven times more health care-related products and services than younger people”.

Medical device companies are proactive in offering solutions to address the demands of the aging population. This demographic trend is related to the following developments:

• Increasing demand for diagnostic equipment to detect all kind of diseases in their early stages, in order to prevent higher costs. As all medicine begins with diagnosis, experts believe that the trends of precision medicine will result in an above average growth in demand for advanced diagnostic devices;
• Increasing demand for specialised wound care and easy-to-use home-care products for diabetes, orthopaedic appliances and dialysis equipment. These products will continue to be sold to an increasing extent as over-the-counter (OTC) products by retail organisations;
• Increasing demand for products that improve the lives of patients at home, including home-care services or devices, self-care products and remotely monitorable diagnostic equipment that enables telehealth.

Tips

• Provide health-care products that are especially useful in the care for elderly patients.

• Consider developing an offer that will place more emphasis on telehealth and home diagnostics products.

• In addition to offering diagnostic devices, consider providing repair services for endoscopy devices. The German repair market for endoscopy devices can be an interesting target market, as it is the largest market in Europe by a long way.

• As advanced diagnostics requires very high investments, consider investing in the supporting products for diagnostic tools. This can involve a wide range of products; for example, tailor-made sterilisation cages for the sterilisation of expensive equipment such as endoscopes.
Technology means opportunities

Despite the pressure on cutting health-care costs, hospitals also want to maintain their high standards of health care. Innovation continues to play an important role. In 2014, more than 11,000 patent applications were filed with the European Patent Office (EPO) in the field of medical technology (7% of the total number of applications), more than any other sector in Europe. Of these patent applications, 41% were filed from European countries and 59% from other countries, with the majority of applications filed from the USA (39%). Examples of innovations that are expected to create market opportunities include:

• 3D medical printing is expected to develop and find implementations in several segments of the medical industry, with its major implementation seen in 3D-printed prostheses;
• Development of minimally invasive surgery by robot technology in combination with endoscopic techniques. Recent deals in this space include the acquisition by Smith & Nephew’s based in the United Kingdom of Blue Belt Technologies based in the USA, a company that develops and commercialises robotics-assisted technologies for use in orthopaedic surgery;
• Involvement of medical devices producers in the development of biotechnology; for example, innovative biomaterials to replace mechanical replacement joints;
• E-health: development of digital patient technologies such as e-prescriptions and electronic health records;
• Mobile health or m-health: development of mobile health technologies such as health apps and mobile solutions such as wearables to facilitate patient care; for example, by collecting patient data with the help of a mobile app;
• Development of rapid, low-cost diagnostics for superbugs in order to contain epidemics;
• Replacement of reusable devices by disposable devices such as surgical instruments;
• Use of imaging technology, especially combined technologies such as X-ray and ultrasound;
• Application of nanotechnology; for instance, semiconductor manufacturing techniques, in medical devices;
• Replacement of traditional latex by low-protein latex, medical-grade plastics or silicone rubber;
• Impregnating of antimicrobial agents into medical devices such as central intravenous catheters;
• Continuing integration of the medical technology and pharmaceutical sector. For example, GlaxoSmithKline recently announced plans to join forces with Alphabet’s Verily Life Sciences to create Galvani Bioelectronics, a joint venture focused on bioelectronic medicines. Their ultimate goal is to develop closed-loop devices that automatically and accurately switch on or off, based on signals in the body that reflect the disease state;
• Introduction and use of mobile medical units for mammography and lithotripsy.

In addition, areas of technological advancement that European medical device producers are looking for include better features of the devices, size reduction and portability, improved reliability and security, and power sources for portable devices.

Tips

• Provide cost-effective and innovative products.
• Conduct research on how your company can provide contributions, such as parts or modules, to European manufacturers’ innovative products. For example, approach European companies that you have in your network and discuss business opportunities with them as a potential supplier of parts or modules for their products.
• Offer your products to the fastest-growing medical devices segments in Europe, such as orthopaedics and prosthetics, dental products, patient aids and high-tech disposables.
Increasing focus on costs and efficiency

Many countries in Europe have faced financial pressure on their health-care budgets in recent years. Consequently, several governments are striving to contain health costs and improve efficiency. Companies are looking toward holistic, coordinated therapies and health-care solutions to offer improved health-care services with better efficiency. As a result, increasing the efficiency of all health-care systems and reducing costs seem to be essential trends that can only be expected to continue during the next years. This provides opportunities for medical devices that can achieve such goals, including, for example:

- Medical devices that facilitate minimally invasive surgery. These can increase the number of operations in day of surgery and ensure a faster turnaround of patients;
- Heart monitors that allow one nurse to take care of a number of patients simultaneously;
- Remote health-care and mobile health devices that collect, manage and analyse large amounts of data. These devices can be expected to support the reduction of health-care costs;
- New entrants in very mature markets, such as those for wound care, coronary stents and orthopaedic devices. Small companies with innovative business models and very competitive prices may be able to enter these markets successfully. It is estimated that some parts of these mature markets will be growing twice as rapidly as the industry as a whole.

Tips

- Benchmark your products against your industry peers in terms of cost-effectiveness.
- Learn more about your competitors in our study of Competition in the medical and laboratory devices industry.
- Provide products that increase efficiency and reduce costs.

Privatisation of public services

Privatisation of health-care is increasingly being considered as an option to keep the cost increase of health-care limited. It could relieve the pressure on public health-care spending and increasing health-care needs due to the ageing population. Some European countries have already privatised part of their health-care in several segments, such as in orthopaedics, plastic and corrective surgery, aesthetic surgery and total pain management. In the Netherlands, “Independent Treatment Centres” have been established as privately run hospital units.

An important change due to the privatisation of health-care is that price has become more important in procurement processes. Whereas in the past, decisions would partly be based on previous experiences and brand names, in the new situation decision-makers have to state clearly why they prefer a certain product. This provides opportunities for lesser-known brands that can offer the same, or even better performance at lower cost.

Insurance companies

Insurance companies will dictate the price level to an increasing extent and reimburse the products as agreed in contracts with health-care institutes. This trend will work to the benefit of suppliers that have good value propositions for their products. In this situation, negotiations between suppliers and insurance companies can be very important in entering the market. If products are accompanied by publications in well-respected literature and from independent doctors, suppliers will enjoy an advantage in these negotiations.
Increasing subcontracting to developing countries
The outsourcing/subcontracting trend is primarily driven by the need of European producers to:
• Reduce the high costs in Europe; for instance, labour and energy costs;
• Focus on other activities, especially product development and marketing.

The majority of subcontracting to developing countries concerns low-value products. Nevertheless, both low- and high-value product segments provide opportunities for producers from developing countries, as long as producers from developing countries can fulfil all requirements. Usually, quality management standards such as ISO and CE certifications help to establish trust with European partners.
One example of cooperation between established European companies on the one hand and companies from developing countries on the other is Medtronic, the world’s largest medical device company headquartered in Ireland, partnering with smaller, entrepreneurial companies in developing countries. This allows Medtronic to reduce its research and development costs, leverage the local company’s knowledge of the market and access a partner’s existing sales and distribution network. In China, for example, Medtronic opened a research and development centre in partnership with Shandong Weigao Group to develop orthopaedic technologies and devices for the local market.

Tips
• Look for European manufacturers/distributors that might be suitable for you to cooperate with. Use resources such as the medical industry portals Qmed and MedicalProducts1.com.

• The future of subcontracting might be influenced by the new Medical Device regulation (see below), which will come into effect in late 2019 or early 2020. Read more about the draft version in this news blog.

New regulatory requirements
The new Medical Device regulation will come into effect in late 2019 or early 2020. Read more about the draft version in this news blog. The two draft regulations are aimed at modernising EU regulations on medical devices and in vitro diagnostic medical devices. The draft regulations strengthen the requirements on placing devices in the market and tighten surveillance once they have been made available.
In addition to European Union regulatory requirements, the next years will be also marked by the implementation of a new ISO standard for connectors (ISO 80369). This new standard will define six types of connectors for several applications (including blood and food), instead of the current worldwide standard of a single format (luer lock) for all applications.
Tips

- Participate actively in the International Medical Device Regulators Forum. Developing countries such as India, China, Mexico and Brazil have benefited from the work of this organisation by taking into account its guidance documents while designing their own regulatory systems.

- Find your opportunity in the connector market by implementing the new ISO 80369 standard. Several large producers in Europe are leaving this market segment, giving more opportunities for suppliers.

Growing demand for home-care medical equipment

There is a general trend that people stay in the hospital for a shorter period. In primary care areas such as diabetes or heart disease, there is much discussion about extending their services to the patient; for example, by adding services tied to adherence or home monitoring.

The home-care medical equipment trend is also related to the collaborative care movement. Collaborative care involves numerous physicians, family members and caregivers, as well as the patients themselves. Some companies develop applications that can help patients to schedule their medications and that inform other members of the care team as well.

Green medical technology

Awareness of sustainability issues is continuing to grow and is becoming even more important among governments, industries and consumers. Government organisations in the Netherlands, for example, have developed a sustainable purchasing programme that includes several medical appliances. Many national governments in Europe have also taken initiatives toward more stringent environmental legislation and measures for the medical industry.

You will have an advantage if you can prove the environmental benefits of your products to the European buyer, such as products that are recyclable or reusable. An important means of doing so is the implementation of a Corporate Social Responsibility (CSR) policy. New studies regarding implemented CSR and process flow control have shown a reduction of >15% in total energy costs and a significantly reduced CO2 footprint.

Tips

- Provide products of which you can prove the environmental benefits.

- Use sustainable materials in your products, such as biodegradable, bio-based or recycled plastics.

- Ensure that your CSR policy is superb and advertise it clearly (on your website and in brochures, for example), preferably using quotes from your CE audit report.


Stricter reimbursement policies

Important changes have also taken place in the reimbursement policies of medical products in all European countries. Governments and insurance companies are demanding hard evidence of the
product’s value, to an increasing extent, or they will not reimburse the medical device.

As mentioned earlier, more and more insurance companies will dictate the price level and reimburse the products as agreed in a contract. In this respect, products that are easy to use, of high quality and price competitive, and products that provide the most benefits to the consumer, are more likely to have the best opportunities in Europe. A new technology or medical product will be able to apply for reimbursement if it can fulfil one or more of a list of requirements, including:

- More treatments done at the same time;
- Shorter recovery time, fewer overnight stays in hospital.

Generally, insurance companies and medical specialist organisations decide together whether a product will be covered by insurance. Although reimbursement policies differ from country to country in Europe, the fundamental dynamics of all reimbursement systems are the same.

### Tips

- Provide products that fulfil one or more of the requirements for reimbursement.
- Enter the European market through European intermediaries or through subcontracting. These partners are aware of reimbursement policies in their specific markets.

### Consolidation continues

According to a survey conducted by KPMG International, companies from the medical devices sector expect to see continued merger, acquisition, separation, inversion, in-licensing and alliance activity in the sector. Most activity will continue to take place in the general equipment segment. This segment is followed by patient monitoring equipment, therapies and supplies. The orthopaedic implants, orthotics and prosthetics sector also remains strong. Large acquisitions in 2016 included Circassia Pharmaceuticals Plc’s €170 million acquisition of Swedish nitric oxide monitoring products developer Aerocrine AB, and Medtronic Plc’s €103 million acquisition of Aircraft Medical Ltd from the United Kingdom, a manufacturer of video laryngoscopes and other hand-held medical devices. In Germany, the largest investments during 2016 happened in three segments: medical electronic devices (22%), dental equipment (17%) and orthopaedics, joints and prostheses (15%).

### Tip

- Look for subcontracting opportunities in the segments with high consolidation activity, as these segments may offer good opportunities.

### Broadening the spectrum of development partners

Leading medical device manufacturers are collaborating with a much broader range of players. As new technologies and data analytics capabilities create opportunities for advances in surgical, diagnostic and health-care monitoring techniques, medical device companies need to work with partners that bring knowledge and capabilities beyond the traditional medical device toolkit. Potential partners include:

- Telecommunications companies, who have expertise in enabling better connectivity of smart health-care devices;
- Insurers and governments, who can collaborate in developing data dictionaries and enabling
broader data collection and analytical techniques;
• IT companies, who can help propel advances in health care-related hardware and software; for example, wearables and related health-tracking apps).

Tip
- Look for opportunities in software development for medical equipment.

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