CBI
Ministry of Foreign Affairs

Exporting anaesthesia equipment and accessories to Europe

Europe was the largest market in the anaesthesia equipment and accessories market in 2016, accounting for around 35% of the global market. Suppliers from developing countries can find opportunities on the large and rapidly growing markets of Europe, such as the Netherlands and Belgium. The rapid adoption of anaesthesia information management systems (AIMS) and new cost-saving technologies are important drivers of further growth in this market.

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1 . Product description

Anaesthesia equipment and accessories refer to instruments and devices used to study anaesthesia and to apply or administer anaesthetics to patients. Anaesthesia is used for rendering patients insensitive to pain while performing surgical procedures. Often, it renders the person unconscious as well. Anaesthesia equipment includes several product categories, which are generally classified into two large groups of products: anaesthesia devices and disposables, and respiratory devices and disposables.

- Anaesthesia devices include anaesthesia workstations, delivery machines (portable and stand-alone), ventilators and monitors.
- Anaesthesia disposables include anaesthesia masks and accessories.
- Respiratory devices include humidifiers, nebulisers, oxygen concentrators, positive airway pressure devices, reusable resuscitators, ventilators and reusable inhalers.
- Respiratory disposables include disposable oxygen masks, resuscitators, tracheostomy tubes and oxygen cannulas.

One CN code, 90189060, has been selected for anaesthesia equipment and accessories referred to

in this survey, unless otherwise stated. The Prodcom code used in the production statistics for anaesthesia equipment and accessories is 32501365.

Quality

Anaesthesia equipment and accessories for the European market must comply with the Medical Devices Directive 93/42/EEC.

Labelling

The requirements for labelling medical devices for the European Union are set out in Annex I, Paragraph 13, of the Medical Devices Directive 93/42/EEC.

The label must state the following:

- the name or trade name and address of the manufacturer. For devices imported into the EU for distribution in the EU, the label, the outer packaging and instructions for use must also state the name and address of the authorised representative if the manufacturer does not have a registered place of business in the EU;
- information required to identify the device and the contents of the packaging, particularly for the users;
- where appropriate, the word STERILE;
- where appropriate, the batch code, preceded by the word LOT or the serial number;
- where appropriate, the date by which the device should be used with safety, expressed as the year and month;
- where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the European Union;
- if the device is custom-made, the phrase “custom-made device”;
- if the device is for clinical investigations, the phrase “exclusively for clinical investigations”;
- any special storage and/or handling requirements;
- any special instructions on how to use;
- any warnings and/or precautions to be taken;
- year of manufacture for active devices other than those covered under (e). This information may be included in the batch or serial number;
- where applicable, method of sterilisation.

Packaging

A key requirement for medical devices is sterile packaging in compliance with EN868 (Part 1). Part 2 to 10 relate to the requirements and test procedures for the various packaging materials. These tests can be used to show that all requirements have been complied with.

There is also an ISO standard for sterile packaging of medical products, ISO 11607. This ISO standard is similar to EN868 and has two parts: Part 1 on the requirements and test procedures for packaging materials, and Part 2 on the validation requirements for packaging processes. While EN868 is mandatory, ISO is a voluntary standard and is often requested by customers.

More general legislation also applicable to medical devices packaging is the EU Packaging and packaging waste legislation, which restricts the use of certain heavy metals as well as setting out other requirements. The EU also has requirements for Wood packaging materials used for transport, such as packing cases, boxes, crates, drums, pallets, box pallets and dunnage.

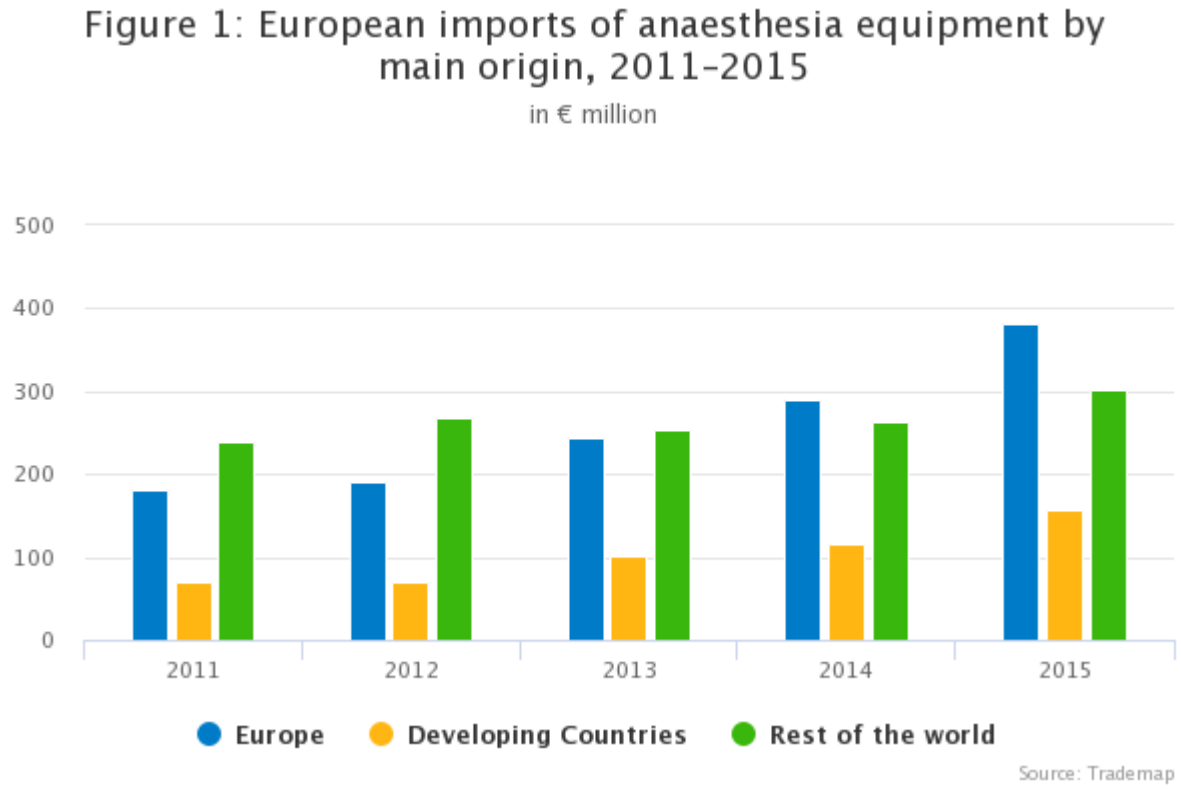
Tip:

- Learn from International Trade Centre (ITC) information on packaging for exporters.

2 . Which European markets offer opportunities for exporters of anaesthesia equipment and accessories?

Imports

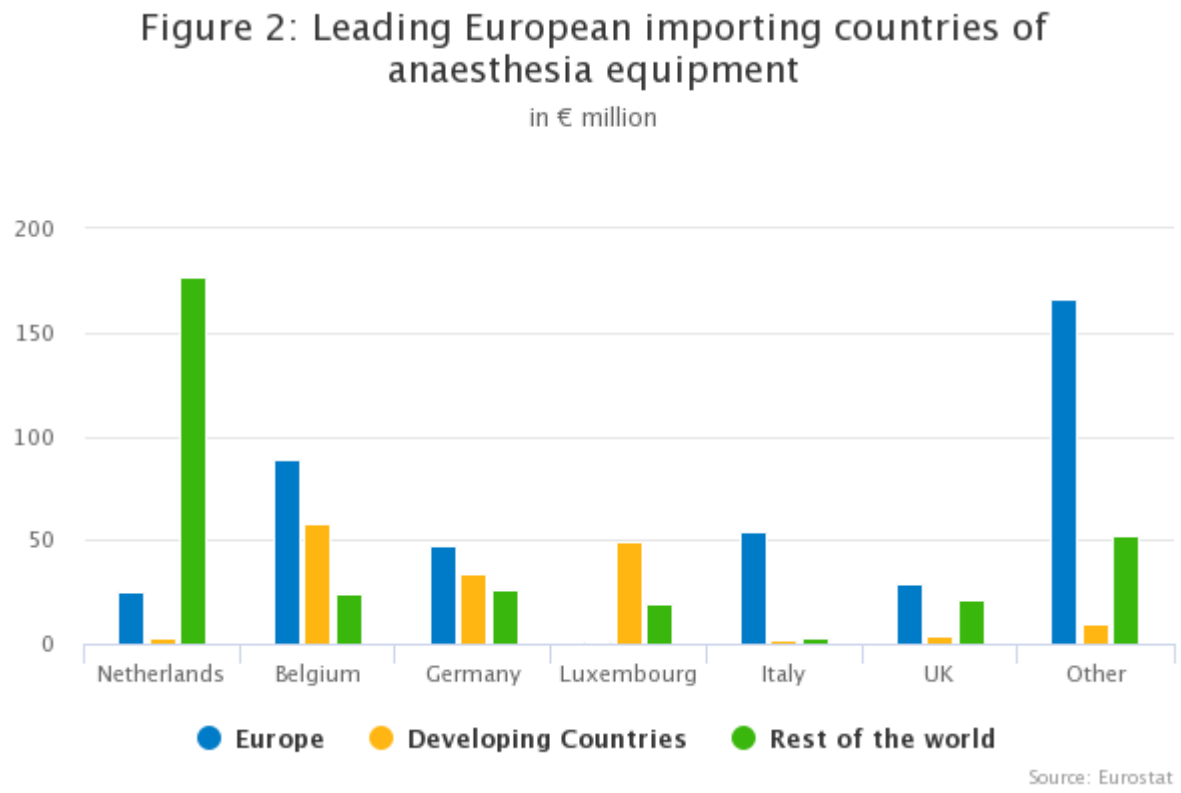
Imports of anaesthesia equipment and accessories to Europe reached €838 million in 2015. The average annual growth in the period 2011–2015 was 14%, with the most significant increase in 2015.



The share of imports from developing countries increased from 14 to 19% in the same period. This share of developing countries is forecast to grow at rates between 3–10% in the foreseeable future. A levelling effect on growth is foreseen, following the very high growth rate of the last five years (by 23% per year).

Although most imports originate from Europe (46% of all imports), this fact is mainly due to the disproportionately high imports coming from Netherlands. The Netherlands is re-exporting a lot of equipment imported from outside Europe.

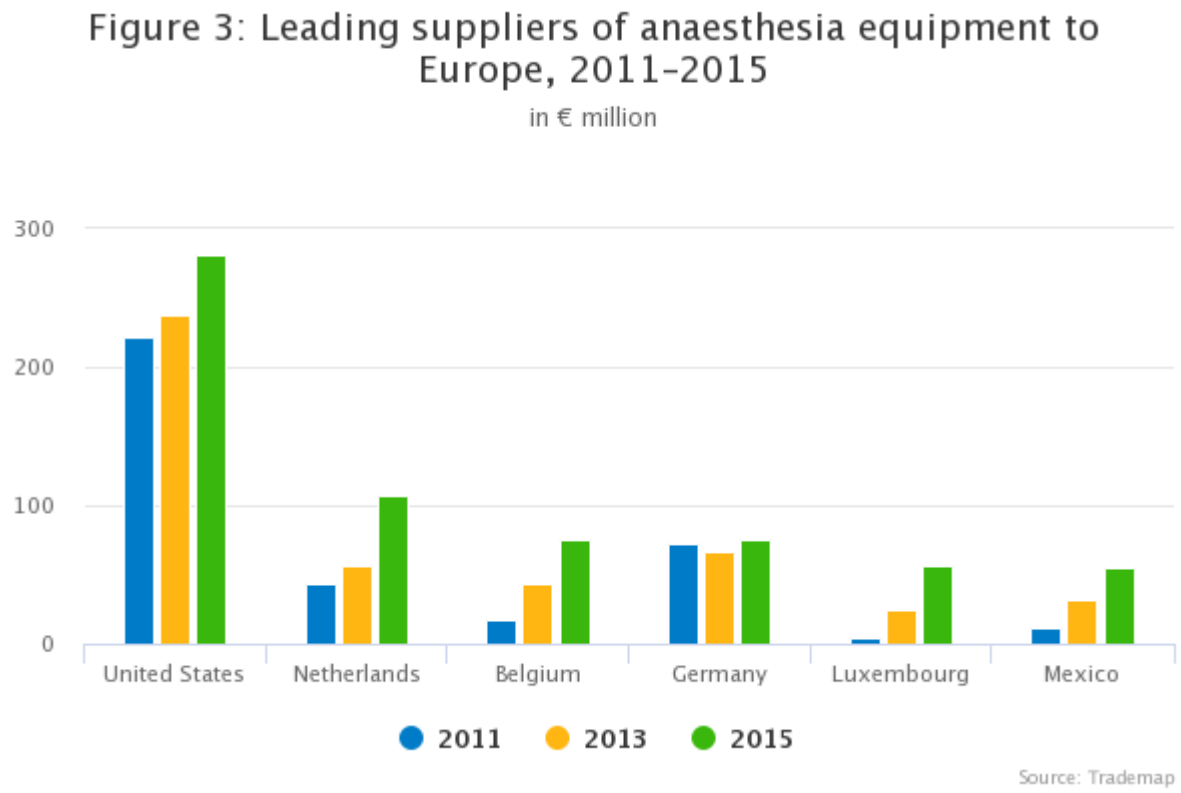
The leading European importer is the Netherlands (23%), followed by Belgium (19%) and Germany (12%). Belgium leads in imports from developing countries, ahead of Luxembourg and Germany. The annual growth in imports between 2011 and 2015 was strongest in the Netherlands (24%) and Belgium (20%).



The fairly strong growth in the import of anaesthesia equipment and accessories is expected to continue over the next few years, in the range of 5 to 10% per year on average.

Leading suppliers

The leading suppliers of anaesthesia equipment and accessories to Europe vary from country to country. Figure 3 below shows that the top three suppliers are the United States, the Netherlands and Belgium. The high growth in supplies from the Netherlands, Belgium and Luxembourg is a main reason for the strong growth in intra-European supplies to the European market (also see Figure 1, the blue column). For the Netherlands, this re-export flow is based on imports from developed countries outside Europe. By contrast, for Belgium and Luxembourg, this flow is based on imports from developing countries.



The leading developing countries supplying to Europe are Mexico (€55 million), China (€37 million), Costa Rica (€29 million) and Malaysia (€7.9 million).

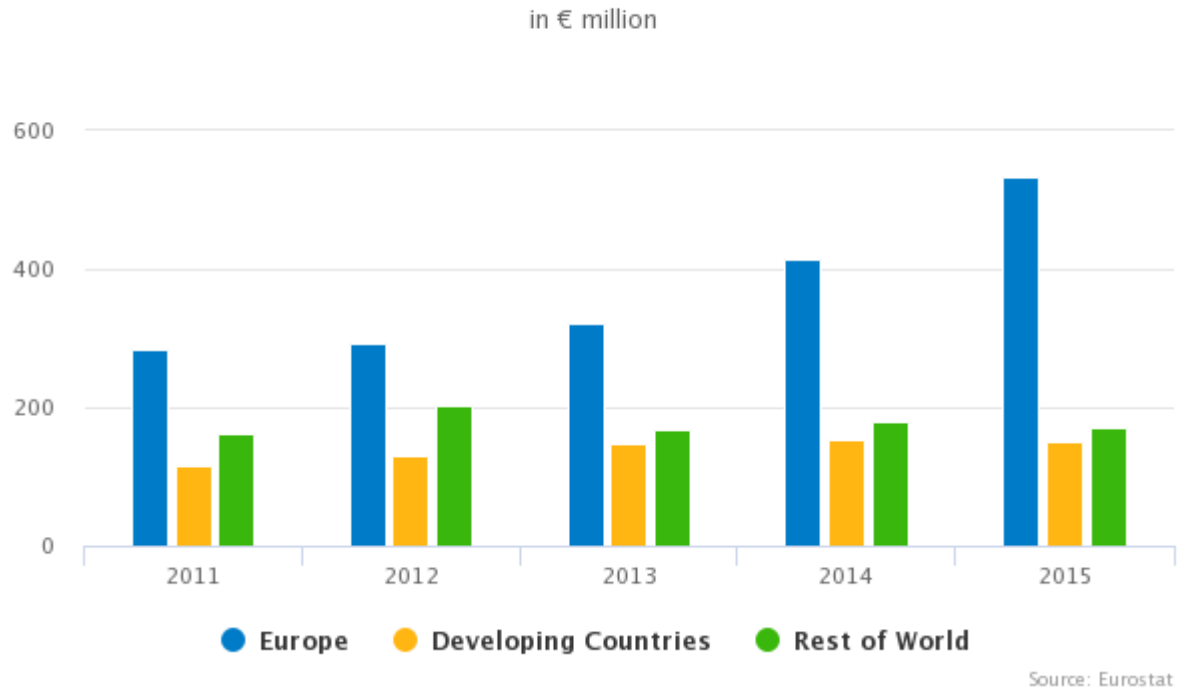
Tips:

- Benchmark your company against your peers in Mexico, China, Costa Rica and Malaysia. Several factors can be taken into account, such as market segments served, perceived price and quality level, and countries served. A useful source to find exporters/producers of anaesthesia equipment and accessories per country is ITC Trademap. Search for "901890 - Instruments and appliances used in medical or veterinary sciences".
- Identify the key importers of your product in selected large or rapidly growing markets. You can start by doing an internet search or reading more about supply chains in Europe in our study of Market channels and segments for medical and laboratory devices.

Exports

Exports of anaesthesia equipment and accessories from Europe reached €856 million in 2015. The average annual growth in the period 2011–2015 was 11.1%. The leading exporter is the Netherlands, ahead of Germany and Belgium.

Figure 4: European exports of anaesthesia equipment to main destinations, 2011-2015



The share of developing countries in European exports is 17.8%, whereas most exports (62.3%) are destined for countries in Europe. This percentage also includes some re-exports of imports from developing countries. For the foreseeable future, the share of developing countries is forecast to remain stable.

The most important export destinations for anaesthesia equipment and accessories outside Europe are the United States, Switzerland, China, Japan and the Russian Federation.

Exports of anaesthesia equipment and accessories from Europe are expected to continue their considerable growth within the next few years, in the range of 5 to 10%.

Tips:

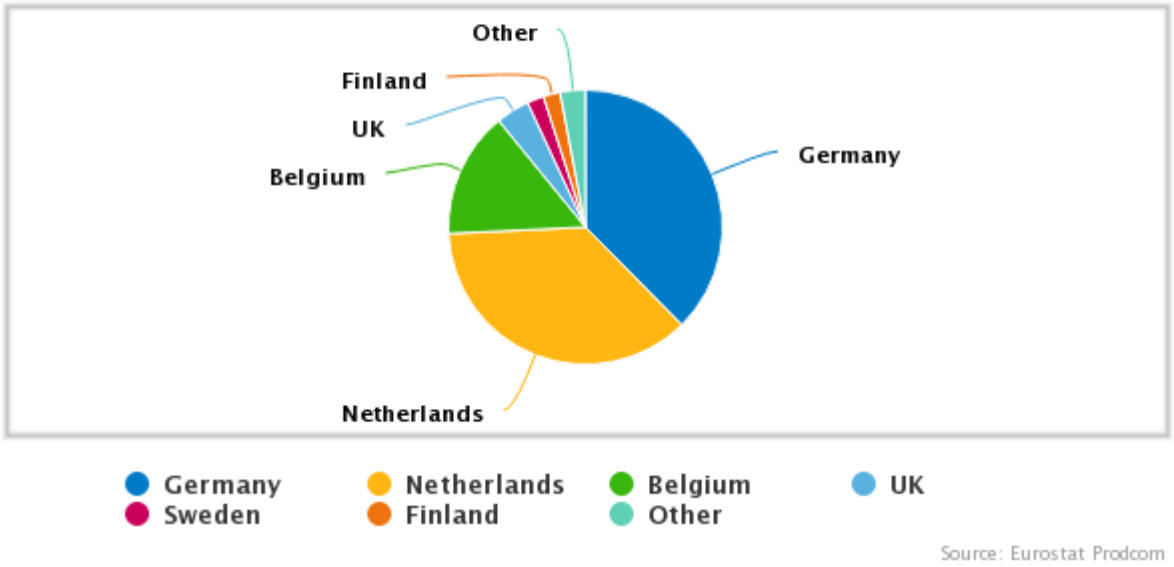
- Learn from European exporters and find opportunities in other growing market for anaesthesia equipment and accessories, such as the United States, Switzerland, China, Japan and the Russian Federation. You can also explore your opportunities in the Asia-Pacific region, as this is the region with the highest expected growth in the near future.
- Learn more about your competitors in our study of Competition in the medical and laboratory devices industry.

Production

The total production in Europe amounted to €865 million in 2015. Growth reached 13.7% per year on average between 2011 and 2015.

Figure 5: Main European producers of anaesthesia equipment

in %



Source: Eurostat Prodcom

Germany is the largest European producer of anaesthesia equipment and accessories, accounting for 38% (€325 million) in 2015. It is followed by the Netherlands (37%; €319 million) and Belgium (15%; €126 million).

The leading European producers of anaesthesia equipment include Drägerwerk AG, Getinge Group, Smiths Medical, Covidien and Philips Healthcare.

Tip:

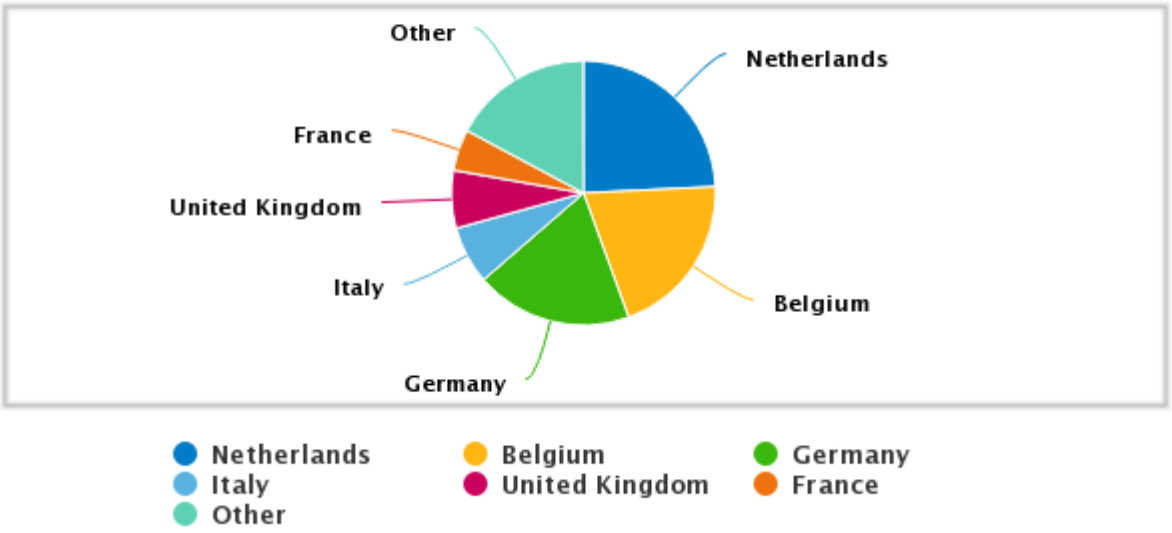
- The presence of producers in Germany, the Netherlands and Belgium offers opportunities for subcontracting to exporters from developing countries.

Demand

Apparent demand in Europe amounted to a total of €845 million in 2015, following 17.4% growth per year on average. The Netherlands is the largest market of anaesthesia equipment and accessories, with a 24% share of the European market. It is followed by Belgium (20%) and Germany (19%).

Figure 6: Main European markets for anaesthesia equipment

in %



Source: Eurostat Prodcom

3 . Which trends offer opportunities on the European market for anaesthesia equipment and accessories?

The ageing population and the increasing health expenditures, especially in Central and Eastern European countries, are two main drivers of growth on the general market for anaesthesia equipment in Europe. On a lower level, one can see the following trends:

Anaesthesia information management systems

There is a large growth in the use of anaesthesia information management systems (AIMS) across Europe. AIMS allow for the automatic collection, storage and presentation of patient data during both the perioperative period and recovery. For this reason, AIMS improve operating room efficiency and increase the quality of care delivered.

Smart equipment

Anaesthesia monitoring devices are expected to attract increasing demand, as they facilitate accurate monitoring of anaesthesia in a patient. Anaesthesia monitoring devices are used to measure the depth of anaesthesia during surgery and to observe patients' physiological state. The highest growth is expected in advanced anaesthesia monitors and other IT-enabled devices such as gas monitors, depth of anaesthesia monitors, MRI-compatible anaesthesia monitors and standalone capnography monitors.

The demand for low-flow anaesthesia machines is expected to show above-average growth, because they are cost-efficient, reduce air pollution and are more suitable for patients who suffer from respiratory diseases.

One of the most recent innovations is the electromagnetic navigation bronchoscopy system. This system is a minimally invasive approach that accesses difficult-to-reach areas of the lungs, aiding in the diagnosis of lung disease and leading to earlier, personalised treatment.

Advances in ventilation systems

The evolution of anaesthesia machines has progressed from stand-alone, non-networked systems to networked anaesthesia workstations that comprise anaesthesia monitors and anaesthesia information management systems (AIMS). The last decade witnessed manufacturers introducing

anaesthesia machines with extra features such as advanced ventilators, additional and new modes of ventilation, graphical screens and loops that offer a clearer picture of the patient, with a major proportion of the ventilators now electronic and driven by software.

The buyer currently has several advanced ventilation options from which to choose, such as synchronised intermittent mandatory ventilation (SIMV), pressure support ventilation (PSV) and pressure-controlled ventilation-volume guaranteed (PCV-VG), with the additional alternative of either updating these systems or purchasing them on a priority basis.

Magnetic Resonance Imaging (MRI) anaesthesia monitoring devices

A recent market trend is the increasing demand for MRI-enabled anaesthesia monitoring devices. Intraoperative MRI offers the advantage of near real-time imaging guidance during surgical procedures. This development is a big advancement compared to surgical techniques based on pre-operation images.

Safety

Innovative techniques and products are constantly being developed in anaesthesia equipment to further increase patient safety. Such innovations include, for example, a regional anaesthetic delivery system that mitigates the risk of nerve injuries and an actuating device that reduces needle misplacement errors.

Disposability

A trend in consumable anaesthesia accessories is to use disposable rather than reusable products. These disposable products can be more cost- and time-effective than reusable products that need to be sterilised after each use. Examples include disposable anaesthesia masks and endotracheal tubes.

Cost saving

The market for stand-alone anaesthesia machines is forecast to exhibit highest-market growth. This growth is driven by the cost-saving technologies that these machines provide. Technologies such as low-flow anaesthesia, efficient anaesthesia agent consumption and recirculation of sample gases result in long-term cost saving.

Refurbished equipment

Increasing demand for refurbished anaesthesia equipment is an important trend on the European health-care market. An important driver of this trend is the fact that many anaesthetists get used to specific equipment and are unwilling or reluctant to change to other types of machines. Another reason for this strong demand is the good availability of spare parts for refurbished equipment.

Tips:

- Invest in R&D to develop innovative, cost-effective solutions.
- Focus on disposable alternatives in consumable anaesthesia accessories.
- Offer bundled solutions of anaesthesia equipment and accessories sold as a package.
- Read magazines and news from European or international sources, such as Anaesthesia News, Anesthesiology News, British Journal of Anaesthesia, European Journal of Anaesthesiology or Medical Device and Diagnostic Industry.
- See CBI Trends for Medical and Laboratory Devices for more information on general trends in the sector.

4 . Which requirements should anaesthesia equipment and accessories comply with to be allowed on the European market?

Mandatory

Anaesthesia equipment and accessories for the European market need CE marking. To obtain this, your products need to comply with the Medical Devices Directive 93/42/EEC. This directive ensures the safety and performance of medical devices. The requirements include a quality system for design, manufacture, and final product inspection and testing (such as ISO 13485).

In 2012, the European Commission presented a proposal to replace the three European medical devices directives with two EU regulations to “achieve a suitable, robust, transparent and sustainable regulatory framework” for the development of safe, effective and innovative medical devices. On 5 October 2015, the Ministers of the European Union countries agreed on a general approach to the package. The new regulations are expected to be implemented by 2018–2020.

Suggested revisions include the extension of the scope of legislation, better supervision of independent assessment bodies, clear rights for economic operators and stronger requirements for clinical evidence.

The final formal adoption is expected on the side of both the Council and the Parliament during the first semester of 2017.

Tips:

- See our study of Buyer Requirements for Medical Devices for more information.
- Consult the European Commission Blue Guide, which sets out how to implement the EU product rules on medical devices.
- See the accompanying guidance documents to assist stakeholders in implementing directives related to medical devices. These documents offer more information on the Medical Devices Directive.
- Keep up to date with the revision of the Medical Devices Directives.

Depending on the specific product, your anaesthesia equipment and accessories may also have to comply with the Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EU. This aims to increase the recycling and/or reuse of the waste of electrical and electronic equipment.

Tip:

- Consult the Frequently Asked Questions (FAQ) on the WEEE Directive.

Additional requirements

Complying with voluntary standards, such as IEC/EN 60601, could help you obtain CE marking for your product.

Other voluntary standards address organisational (such as ISO 13485), environmental and social/labour requirements.

Governments, industries and consumers are increasingly aware of sustainability issues. The Ecodesign Directive 2009/125/EC helps to improve the energy efficiency of products and is complemented by the Energy Labelling Directive for labelling requirements.

In 2014, the European Commission published the Green Public Procurement (GPP) Criteria for Electrical and Electronic Medical Devices (Healthcare EEE), a voluntary instrument with clear, verifiable, justifiable and ambitious environmental criteria based on a life cycle approach and scientific evidence.

Recently, the concept of Corporate Social Responsibility (CSR) has become more important in the medical device sector. Buyers are increasingly selecting suppliers based on their ethical and social responsibility measures.

For anaesthesia equipment and accessories, no duty is levied on imports to EU Member States from outside the EU.

Tips:

- Visit the EU Export Helpdesk for requirements, tariffs, statistics and preferential arrangements
- Check the ITC Market Access Map for technical standards and the ITC Standards Map for voluntary standards.
- Click on TC 76, 84, 194 and 210 in the ISO Catalogue for an overview of ISO standards.
- Search EN norms in the online shop of the British Standards Institution.
- Consult the Frequently Asked Questions (FAQ) on the Ecodesign Directive.
- Use sustainable materials in your products, such as biodegradable, bio-based and recycled plastics.
- Consult the Frequently Asked Questions (FAQ) on Green Public Procurement.
- Keep your CSR policy in order and advertise it clearly; for instance, on your website and in brochures, preferably using quotes from your CE audit report.

5 . What competition do I face on the European markets for anaesthesia equipment and accessories?

As competition for anaesthesia equipment and accessories does not differ significantly from the Medical and Laboratory Devices sector, see CBI Competition for Medical and Laboratory Devices and CBI Top 10 Tips for Doing Business with European Buyers for an overview.

6 . Through which channels can you get anaesthesia equipment and accessories on the European market?

As market segments and channels for anaesthesia equipment and accessories do not differ significantly from the Medical and Laboratory Devices sector in general, see CBI Market Channels and Segments for Medical and Laboratory Devices for an overview.

Tips:

- Read our study of Finding Buyers in the Medical and Laboratory Devices sector to get many tips on finding the right match in Europe.

- Make use of databases to find potential buyers, such as ESTA Healthcare.
- Check the websites of European associations for member lists or databases. European associations are Medtech Europe (Eucomed), the European Association of Cardiothoracic Anaesthesiologists, the European Hospital and Healthcare Federation, the European Society of Regional Anaesthesia & Pain Therapy, the European Society for Paediatric Anaesthesiology and the European Society of Anaesthesiology.
- Consider visiting trade fairs or events to meet potential buyers: Euroanaesthesia (UK), MEDICA (Germany) and Medtec Europe (Germany).

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