

CBI Ministry of Foreign Affairs

CBI Product Factsheet:

Bandages, gauzes and dressings in Germany, Austria and Switzerland

Introduction

The market for bandages, gauzes and dressings in Germany, Austria and Switzerland has grown steadily over the last few years and is expected to continue to do so in the foreseeable future. There is increasing demand for innovative, cost-effective solutions and products for the care of elderly patients. Imports of bandages, gauzes and dressings to Germany, Austria and Switzerland reached €933 million in 2014. The share of imports from developing countries has been stable at between 18 and 20%. Germany is the largest importer, making it the most interesting country of these three German-speaking and neighbouring countries.

Product description

Bandages, gauzes and dressings are medical disposables and are generally used only once. Medical disposables are usually low technology products of high volume and low value.

Bandages, gauzes and wadding

A bandage is cloth or other material of varying shape and size that is applied to a body part to apply pressure, absorb drainage, prevent motion or retain surgical dressings. Gauze is a bleached cotton cloth with an open weave used for dressings, bandages and absorbent sponges. Wadding is carded cotton or wool in sheets, used for surgical dressings. Generally, these dressings can absorb moderate amounts of exudates.

Adhesive dressings

Adhesive dressings are plasters or tape used for wound healing. Adhesive dressings can be made from fibre (100% cotton) and woven into a fabric-like material. These dressings are also often non-woven from various materials with the fibres arranged to present a woven-like appearance. Adhesive dressings can be impregnated with substances and are available in many sizes and forms, such as pads, strips, ropes, sponges, tubes and ribbons. Non-woven materials are gaining popularity because they can easily be impregnated with anti-bacterial agents.

One CN code has been selected for bandages, gauzes and dressings. See Table 1, which also shows the Prodcom code used in production statistics for bandages, gauzes and dressings.

Table 1: Selected products based on CN and Prodcom nomenclature

CN code	Prodcom code	Description
3005	21202420 21202440	Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes

Source: CN and Prodcom Nomenclature

In this survey, 'bandages, gauzes and dressings' refers to the product selection in Table 1, unless stated otherwise.

Quality

Bandages, gauzes and dressings for the European market must comply with the <u>Medical Devices Directive</u> <u>93/42/EEC</u>. For more information, see Compliance Requirements below.

Labelling

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

The label must state the following:

- The name or trade name and address of the manufacturer. For devices imported into the European Union for distribution in the European Union, the label, the outer packaging, and instructions for use must contain the name and address of the authorised representative if the manufacturer does not have a registered place of business in the European Union;
- Information essential to identify the device and the contents of the packaging especially 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, in safety, expressed as in year and month;
- Where appropriate, a statement 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 label must state 'custom-made device';

- If the device is for clinical investigations, the label must state 'exclusively for clinical investigations';
- Any special storage and/or handling requirements;
- Any special instructions for use;
- Any warnings and/or precautions to be taken;
- Year of manufacture for active devices other than those covered under (e). This indication may be included in the batch or serial number;
- Where applicable, method of sterilisation.

Packaging

Medical devices require sterile packaging in compliance with EN868 (part 1). Part 2 to 10 relate to the requirements and test procedures for the 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, <u>ISO 11607</u>. This ISO standard is very 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 of packaging processes. While EN868 is mandatory, ISO is a voluntary standard and is often requested by customers.

More general legislation applicable to medical device packaging is the European <u>Packaging and packaging waste</u> legislation. This legislation restricts the use of certain heavy metals, and states other requirements. The EU also has requirements for <u>Wood packaging materials used for transport</u> (WPM), such as packing cases, boxes, crates, drums, pallets, box pallets, and dunnage.

The International Trade Centre (ITC) provides additional information on packaging for exporters.

Demand

Imports

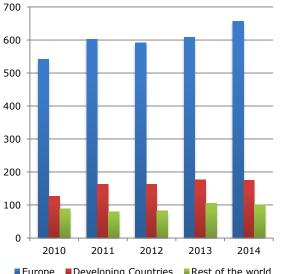


Figure 1: Imports of bandages, gauzes and dressings to Germany, Austria and Switzerland, by main origin, € million, 2010-2014

■ Europe ■ Developing Countries ■ Rest of the world *Source: Trademap*

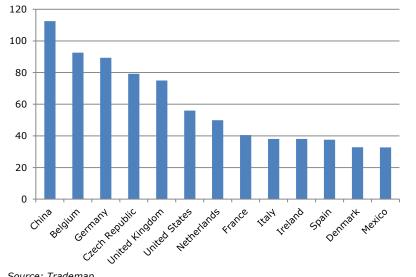


Figure 2: Leading suppliers of bandages, gauzes and dressings to Germany, Austria and Switzerland, € million, 2014

Source: Trademap

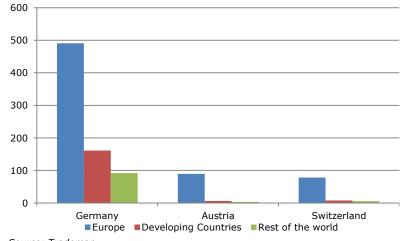
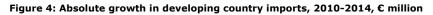
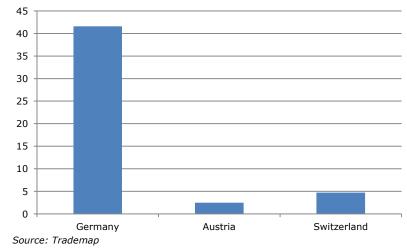


Figure 3: Imports of bandages, gauzes and dressings to Germany, Austria and Switzerland by main origin, € million, 2014

Source: Trademap





- Imports of bandages, gauzes and dressings to Germany, Austria and Switzerland reached €933 million in 2014. Average annual growth in 2010-2014 was 5.4%.
- The developing country share of imports ranged from 18 to 20% in this period. Most imports originate from intra-Europe sources (70% of all imports). For the foreseeable future, the developing country share is forecast to be relatively stable between 18 and 20%.
- The leading importer is Germany at 80%, followed by Austria (11%) and Switzerland (10%). Germany also leads in developing country imports, ahead of Austria and Switzerland.
- Imports of bandages, gauzes and dressings are expected to show moderate growth in the next few years, in the range of 3 to 5%.

Leading suppliers

- Most leading suppliers of bandages, gauzes and dressings to Germany, Austria and Switzerland are developed countries.
- The main developing countries on the list of leading suppliers are China (\leq 113 million) and Mexico (\leq 33 million).
- Other developing countries exporting bandages, gauzes and dressings to Germany, Austria and Switzerland are India (€11 million), Egypt (€6.9 million), Thailand (€5.3 million), South Africa (€2.6 million), Colombia (€1.7 million) and Turkey (€0.6 million).

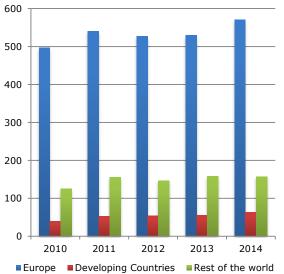
Tip:

• Benchmark your company against your peers in developed countries, China and Mexico. 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 bandages, gauzes and dressings

per country is the ITC Trademap.

Exports

Figure 5: Exports of bandages, gauzes and dressings from Germany, Austria and Switzerland, by main destination, € million, 2010-2014



Source: Trademap

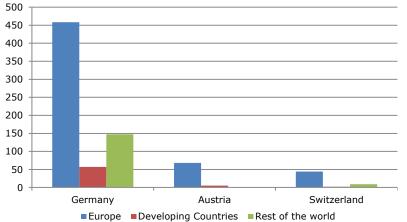
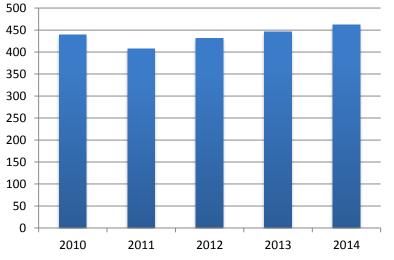


Figure 6: Exports of bandages, gauzes and dressings from Germany, Austria and Switzerland by main destination, € million, 2014

- Exports of bandages, gauzes and dressings from Germany, Austria and Switzerland amounted to €792 million in 2014. Average annual growth in 2010-2014 was 4.6%.
- The developing country share of exports is 8.1%, as most exports (72%) are destined for European countries. This
 also includes some re-export of imports from developing countries. For the foreseeable future, the developing
 country share is forecast to show small growth in the range of 0-3%.
- The leading exporter is Germany, accounting for 84%, far ahead of Austria (9%) and Switzerland (7%).
- Of the total of €792 million, €81 million of exports go to France, with Italy in second position (€71 million), followed by the UK (€68 million).
- The European exports of bandages, gauzes and dressings are expected to show moderate growth in the next few years, in the range of 2 to 4%.

Production and apparent demand

There are no statistics available for Switzerland on the production of and demand for bandages, gauzes and dressings. The data here are for Germany and Austria.





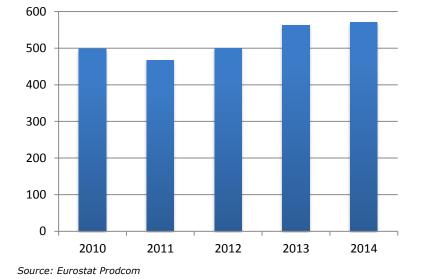
Source: Eurostat Prodcom

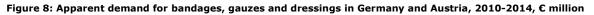
Austria did not produce bandages, gauzes and dressings between 2010 and 2014. After a dip in 2011 (€408 million), production in Germany totalled €462 million in 2014, following an average annual increase of 4.3% in the period 2011-2014.

Source: Trademap

Tip:

• The presence of producers in Germany offers opportunities for subcontracting for developing country exporters. Links to databases of producers of bandages, gauzes and dressings can be found in Useful Sources below.



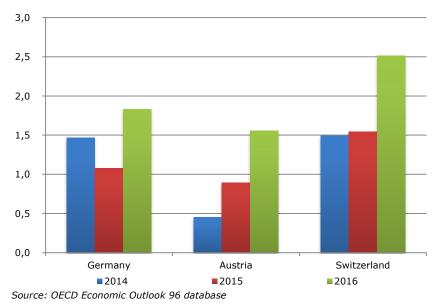


• Apparent demand in Germany and Austria totalled €570 million in 2014, after an average annual increase of 3.4% in the period 2010-2014.

• Germany is the dominant producer of bandages, gauzes and dressings at 96%, and has by far the largest apparent demand. Only 4% of demand comes from Austria.

Macroeconomic indicators





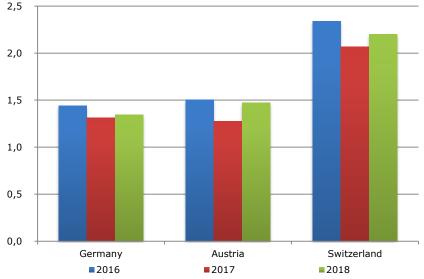


Figure 10: Number of senior citizens (65+), percentage change on the previous year

Source: Eurostat EUROPOP2013

- The major determinant of demand for bandages, gauzes and dressings is spending in the medical sector. In turn, this demand is stimulated by economic growth and an ageing population (an ageing population needs more medical care). In each focus country, Gross Domestic Product (GDP) and the number of senior citizens are expected to show continued growth year-on-year in the foreseeable future. This is a good basis for estimating demand for and growth in imports in the coming years.
- Profitability of bandages, gauzes and dressings imports is influenced by the euro/US dollar exchange rate, because many medical devices and disposables sourced globally are paid for in US dollars. While the euro/US dollar exchange rate was not forecast to go beyond 0.80 until 2020, the exchange rate was between 0.88 and 0.93 in the period March-October 2015. This has a large impact on the price level of imports. If this situation continues for some years, it will have a negative impact on European imports paid for in US dollars versus local European production.

Tip:

• If the Euro stays at approximately US\$ 0.90, developing country producers should increasingly focus on cost reduction to remain competitive in the European market.

For more information, see CBI Trade Statistics for Medical and Laboratory Devices.

Trends offering opportunities

Smart bandages, gauzes and dressings

Researchers worldwide are developing newer, smarter and more effective bandages. Not all are already on the market, but some are. Technological inventions in bandages include bandages that change colour to indicate infection, bio-electronic bandages, and preventive care in bandaging that can detect tissue damage before it becomes visible.

Rise in recreational activities

An increasing number of recreational activities in all age groups in Europe will drive market growth in bandages, gauzes and dressings. Activities such as trekking can result in multiple cuts and abrasion requiring the application of bandages, gauzes and dressings, and augment the demand for these products. The rising number of incidences in the kitchen while cooking will further increase the growth of the market for bandages, gauzes and dressings.

Ageing population

The aging population will boost market growth in bandages, gauzes and dressings, since elderly people met with small accidents, such as falls on stairs. There will also be more need for specific types of bandages, gauzes and dressings, for instance, for bedsores, longer wound healing and other types of wound care that increase with age.

Tips:

- After recognising the options that technological inventions can offer in bandages, gauzes and dressings, you can invest in R&D to develop innovative solutions.
- Solutions that result in more cost-efficient healthcare, offer opportunities in Germany, Austria and Switzerland for bandages, gauzes and dressings.
- Offer bandages, gauzes and dressings that are especially useful in the care of elderly patients.

For more information on general trends, see <u>CBI Trends for Medical and Laboratory Devices</u>.

Market requirements

Mandatory

The EU has a <u>Mutual Recognition Agreement</u> (MRA) with Switzerland, covering the recognition of conformity assessments irrespective of the origin of products including medical devices. This means that certificates issued in the European Union, in accordance with European legislation, are equivalent to those issued in Switzerland, in accordance with Swiss legislation.

Bandages, gauzes and dressings for the EU market require CE Marking. To obtain this, your products must comply with the <u>Medical Devices Directive 93/42/EEC</u>. This directive ensures the safety and performance of medical devices, including disposables. The requirements include a quality system for design, manufacture and final product inspection and testing (such as, <u>ISO 13485</u>).

In 2012, the European Commission presented a proposal to replace the three <u>European medical devices directives</u> with two European 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.

Tips:

- Consult the European Commission <u>Blue Guide</u> that sets out how to implement the EU product rules on medical devices.
- For more information on the Medical Devices Directive, see the accompanying <u>guidance documents</u> to assist stakeholders in implementing directives related to medical devices.
- Keep up-to-date with the <u>revision of the Medical Devices Directives</u>.

Additional requirements

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

Other voluntary standards provide organisational (for instance, <u>ISO 13485</u>), environmental and social (labour) requirements.

Governments, industries and consumers are becoming increasingly aware of sustainability issues. Recently, the concept of <u>Corporate Social Responsibility</u> (CSR) has also become more important in the medical device sector. Buyers are increasingly selecting suppliers based on their ethical and social responsibility measures.

For bandages, gauzes and dressings, no duty is levied on European imports from countries outside the EU.

Tips:

- For more information on gaining access to the EU market, see:
- <u>EU Export Helpdesk</u> for requirements, tariffs, statistics and preferential arrangements
- ITC Market Access Map for technical standards
- ITC Standards Map for voluntary standards.
- In the <u>ISO Catalogue</u>, click on TC 76, 84, 194 and 210 for an overview of ISO standards.
- Search EN norms in the <u>online shop of the British Standards Organisation</u>.
- Use sustainable materials in your products, such as biodegradable, bio-based and recycled plastics.
- Have 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.

Competition

As competition for bandages, gauzes and dressings does not differ significantly from the Medical and Laboratory Devices sector, see <u>CBI Competition for Medical and Laboratory Devices</u> and <u>CBI Top 10 Tips for Doing Business with European</u> <u>Buyers</u> for an overview.

Trade channels and market segments

As market channels for bandages, gauzes and dressings do not differ significantly from the Medical and Laboratory Devices sector, see <u>CBI Market Channels and Segments for Medical and Laboratory Devices</u> for an overview.

Potential trading partners include:

Germany

- <u>B. Braun</u> manufacturer
- BSN medical manufacturer
- <u>Freudenberg Nonwovens</u> manufacturer
- HARTMANN manufacturer
- <u>imeco</u> manufacturer
- <u>Innovatec Microfibre Technology</u> manufacturer
- Lohmann & Rauscher manufacturer
- Sandler manufacturer
- <u>Servoprax</u> distributor

Austria

- <u>AMEX</u> distributor
- Egeria manufacturer
- <u>Ligamed</u> manufacturer
- sorbion austria manufacturer and distributor

Switzerland

- <u>gd medical</u> distributor
- <u>Marcel Blanc</u> distributor
- <u>publicare</u> distributor
- Sanello distributor
- <u>Tinovamed</u> distributor
- <u>Wernli</u> manufacturer

Useful sources

- Finding prospects: ESTA Healthcare, MedicalExpo, Qmed
- National associations: <u>Austrian Association of Medical Device Manufacturers and Suppliers</u>, <u>Federation of Swiss</u> <u>Medical Devices Trade and Industry</u>, <u>German Medical Dealers Association</u>, <u>German Medical Technology Association</u>, <u>SPECTARIS Trade Association Medical Technology</u>
- European associations: <u>EDANA/MEDECO</u>, <u>Medtech Europe (Eucomed)</u>, <u>European Hospital and Healthcare Federation</u>, <u>European Wound Management Association</u>
- Magazines and news: Devicemed, Medical Device and Diagnostic Industry, Journal of Wound Care
- Trade fairs: MEDICA (Germany), Medtec Europe (Germany)

For more information, see <u>CBI Finding Buyers</u> in the Medical and Laboratory Devices sector.

CBI Market Intelligence

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This survey was compiled for CBI by Globally Cool – Creative Solutions for Sustainable Business in collaboration with CBI sector expert Leendert Santema.

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