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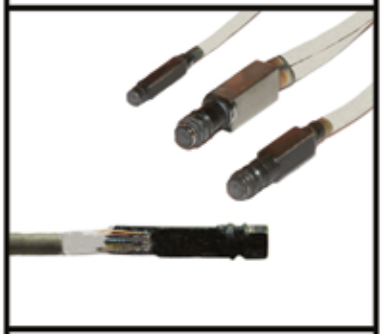

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Industry puts its money on the No. 1: MEDICA 2012 sets new records

The industry continues to put its money on **MEDICA in 2012**, as it features the right balance of quality and quantity in term of supply and demand, with the broad spectrum of topics and the clearly organized structure at **MEDICA** proving to be a genuine advantage. The market does not focus specifically on certain product segments, but on process-oriented techniques for the diagnosis and treatment of various disease patterns together with the appropriate solutions.

On the basis of the advance registrations for **MEDICA 2012** – World Forum for Medicine (14 – 17 November) received to date, we can expect a similar level of exhibitor participation to that seen last year, with over **4,500 exhibitors from at least 60 different countries.** A highlight is the fact that the number of bookings from abroad has once again risen, reflecting the high level of international participation, underlining MEDICA's role and appeal as a market platform for global business.
In a day and age when innovation on its own isn't everything that counts, but the benefit is critically challenged and the application and treatment benefits of new devices and processes need to be clearly demonstrated, providing information and entering into professional dialogue with and between experts take on particular significance.

MEDICA makes this link between technical applications and their application with regard to specific disease patterns by the interaction between the trade fair, with its integrated themed areas such as the **MEDICA HEALTH IT FORUM** (previously known as **MEDICA MEDIA**, in Hall 15), **MEDICA VISION** (innovation forum for research institutions, in Hall 3) and the **MEDICA PHYSIO FORUM** (in Hall 4) and the **MEDICA Congress** (Congress Center Düsseldorf/ CCD South). The **MEDICA** Congress, which has regularly welcomed over **5,000 visitors** in recent years, and featured some 200 seminars and courses, is the largest interdisciplinary advanced training forum in the field of medicine in Germany, with lectures focusing on key issues such as oncology, cardiology and age-related diseases like diabetes.

New programme highlights

The communication of knowledge and the demonstration of the specific practical relevance is embedded in MEDICA's DNA, which was launched under the name **"Diagnostikwoche"** (Diagnostic Week) as a congress for laboratory medicine in 1969, accompanied by a trade exhibition, and has grown from humble beginnings with just 4,700 visitors and 135 exhibitors to become the world's largest and leading fair in the healthcare sector.

Gradually, in parallel to the increasing resonance both from the exhibitors and the visitors, the programme of the congress held in parallel to the fair and the forums integrated in the fair itself was expanded, with a clear focus on the topical interests of the healthcare professionals who attended the events, and taking current developments in science, research and the health industry into consideration.

And we are continuing to follow this successful path, with another new programme highlight being launched at MEDICA 2012: the **MEDICA ECON FORUM** organized by the Techniker Krankenkasse (TK, a German health insurance company), which will focus specifically on topics geared to the issued of interest to decision-makers in the health care system as well as presenting the new self-image of the insurance companies, which have started playing an active role in shaping the health care system.

Through the increasing improvement in the range of services they provide and the rise in the number of selective contracts, German health insurance companies have metamorphosed from 'payers' into 'players'. They now question the effectiveness of new techniques, and if these new techniques are indeed effective, they are willing to bear the cost of state-of-the-art treatment methods in favor of good treatment for their members. **MEDICA** will pick up on this development with an appropriate forum.

Another new event this year is **"FutureCare"**, a joint stand presented in cooperation with the IT industry association BITKOM, covering about 350 m (in Hall 15) which will feature at current developments and solutions for IT-based health care. The **"FutureCare Health Course"** will depict scenes from the different areas of the health care system and illustrate them with medically relevant case studies on various guided tours, featuring, for example, the use of the electronic health card and the health professional card, the electronic patient and health record, doctor-to-doctor communication, doctor search and evaluation portals and the use of mobile devices in surgeries and hospitals as well a mobile and inpatient care.

MEDICA 2012

This year will also see the return of the **MEDICA WOUND CARE FORUM,** which was successfully launched in 2011 (current trends and new approaches to treating chronic wounds, in Hall 6) and the **MEDICA TECH FORUM** (in Hall 12), which was launched in 2010, and includes lectures in English on current trends in medical technology, for instance looking at topics such as clinical innovation and life cycle management and hospital hygiene concepts.

The key topics at MEDICA (which featured 4,571 exhibitors in 2011), clearly laid out in the different halls, are: electromedicine/medical technology (over 2,400 exhibitors), laboratory technology/diagnostics, physiotherapy/orthopaedic technology, commodities and consumables, information and communication technology, medical furniture and specialist furnishings, and building technology for hospitals and doctors' surgeries.

A strong duo for the entire process chain

COMPAMED 2012 will take place in parallel to **MEDICA 2012.** With over 600 exhibitors at last year's **COMPAMED**, this is the leading market platform for suppliers to the medical technology industry (14 - 16 November). This unique combination allows **MEDICA** and **COMPAMED** to represent the entire process chain and the full range of medical products, devices and instruments. Together, they fill the whole Düsseldorf trade fair complex. In 2011 the two fairs welcomed a total of 134,500 trade visitors, 16,000 of whom were specifically interested in the topics covered by **COMPAMED.**

For further information:
www.medica.de / www.compamed.de.

Source: www.medica.de

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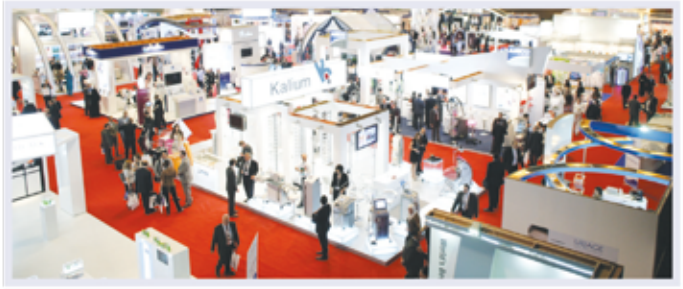

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CMEF 2012

67th CMEF Post Show Report

The grand opening of 67th China International Medical Equipment Fair (CMEF) was held on Apr. 17, 2012 at Shenzhen Convention and Exhibition Center. With extended scale, featuring almost 6,000 booths and an exhibition area of 120,000 square meters, the expo hosted more than 2,600 exhibitors from 24 countries including pavilions from US, Germany, Japan, Korea, France, UK, Belgium, Switzerland, Malaysia etc. and 35 domestic exhibition groups across China and regions of Taiwan, HK, and Macao. The international exhibition area reached around 4,000 square meters. In the four-day exciting period, CMEF attracted 82,360 professionals from 125 countries. There were over 600 new medical products showcased, revealing the fast growing R&D of medical industry.

CMEF Highlights

- **Innovative Technology, Intelligent Healthcare**

Making "Innovative Technology, Intelligent Healthcare" as the theme the 68th CMEF has gathered 2,600 exhibitors from 24 countries and regions showing the most advanced medical technology and innovative products. The 5th Annual In-Vitro Diagnostics China Summit and the 4th China Integrated Medical Imaging Summit were held concurrently. In addition, over 30 professional conferences and seminars covering the innovative technology and products were held during the show. CMEF faces the whole medical devices industry and displays medical equipments and relative services of the entire industry chain. By innovation, trading, learning and networking CMEF has gathered the intelligence and built up the "cloud" platform of the industry.

- **New Products**

In order to make a wonderful performance on CMEF many exhibitors chose to launch new products during the exhibition, such as GE, Philips, Mindray, Siemens, Neusoft, Anke, Landwind, Yuyue, Sinopharm, Shinva and Hitachi etc. According to the statistics around 600 most advanced technology and products had been launched during the show.

- **Trading & Networking**

Besides the launch of innovative products CMEF has always been an important platform for the trading of medical devices products. Over 10,000 kinds of products were displayed during the show. Because of the increasing demand of exhibit space CMEF has fully made use of all the space of the show venue including the outdoor space and the aisle on the 2nd level so as to accommodate more companies to get involved in this "Cloud" platform.

- **Academic Conferences and Seminars**

A series of high level academic conferences and seminars were held during the exhibition, which had brought intensive academic atmosphere to CMEF.

For more information please visit: www.cmef.com.cn/en

KIMES 2012

The inception of future medical technology… KIMES

The 29th Korea International Medical & Hospital Show will take place at COEX in Seoul from 21st to 24th March in 2013. The Asian's premier medical event has been growing as the hub of attraction for all those involved in the medical and health care industries. With excessive demands from the Korean consumers, the development of the medical industry in Korea is remarkably fast-growing. In the circumstances, KIMES's filling of the role of the platform where manufacturers and consumers can find their satisfactions.

Korea, the Hub of Healthcare Technology

In Korea, medical teams have particularly keener interest and show a higher level of research on new medical technology such as robotic surgery and the U-health care system based on perfect IT infrastructure. And the governmental investment and effort to activate health care industry has been increased as well. In this background, global companies have been constantly making investments to the foothold in charge of exportation in the world and building R&D centers in Korea. Korean medical industry being in the limelight as the national driving force for new growth will provide new potentials to the medical industry gradually evolving.

KIMES Heading toward the Global Medical Market

KIMES that has been growing along with local medical equipment industry now raises itself as the world's prominent specialized medical exhibition. In KIMES 2012 Exhibition, 458 domestic companies and also 978 companies from total 30 states including America, Germany, England, Japan, Italy, Taiwan, or China participated to introduce up to 30,000 or so items such as advanced medical equipment, hospital equipment, medical information, and medical products. We expect that up to 60,000 visitors will come to KIMES 2013 where 1,200 or so companies from 35 companies will join in the exhibition with the scale of 38,000m^2. Also, KIMES exhibition approved by the Global Association of the Exhibition Industry (UFI) has been playing its roles as a bridgehead fully heading toward the global medical market as a specialized international medical exhibition matching its reputation. The unique Korean medical show is suggesting the direction for the future medical technology through projected 60,000 visitors who would be obtaining information on all the current and future trends at the North-East Asia's premier medical event.

The range of exhibits at KIMES includes consultation, diagnosis central supply, clinical examination, hospital accommodation, emergency equipment, radiology, medical information system, surgical apparatus, oriental medicine, cure apparatus, pharmaceutical, physiotherapy apparatus, obesity cure, healthcare, ophthalmic apparatus, medical device component, medical service, dental apparatus, disposable apparatus and others.

The next edition of KIMES will be held from 21-24 March 2013 in Seoul, for more information please visit www.kimes.kr.

MEDICARE TAIWAN
Taiwan Int'l Medical & Healthcare Exhibition
Sustainable Paths to Good Care

JUNE 20-23 2013

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- Rehabilitation Equipment, Mobility Aids, and Health Care Products
- Electromedical Equipment, IT/ Mobile Technology in Health Care
- Laboratory, Medical Test and Hospital Equipment
- Diagnostics, Disinfection and Sterilization Equipment
- Surgical, Dental and Orthopaedic Equipment
- Medical Services and Publications
- Manufacturing Equipment, Parts, Accessories & Materials
- Media

Exhibition Activities

- Seminars & Forums
- 1-on-1 Procurement Meetings
- New Product Launch Announcement

GENERAL INFORMATION

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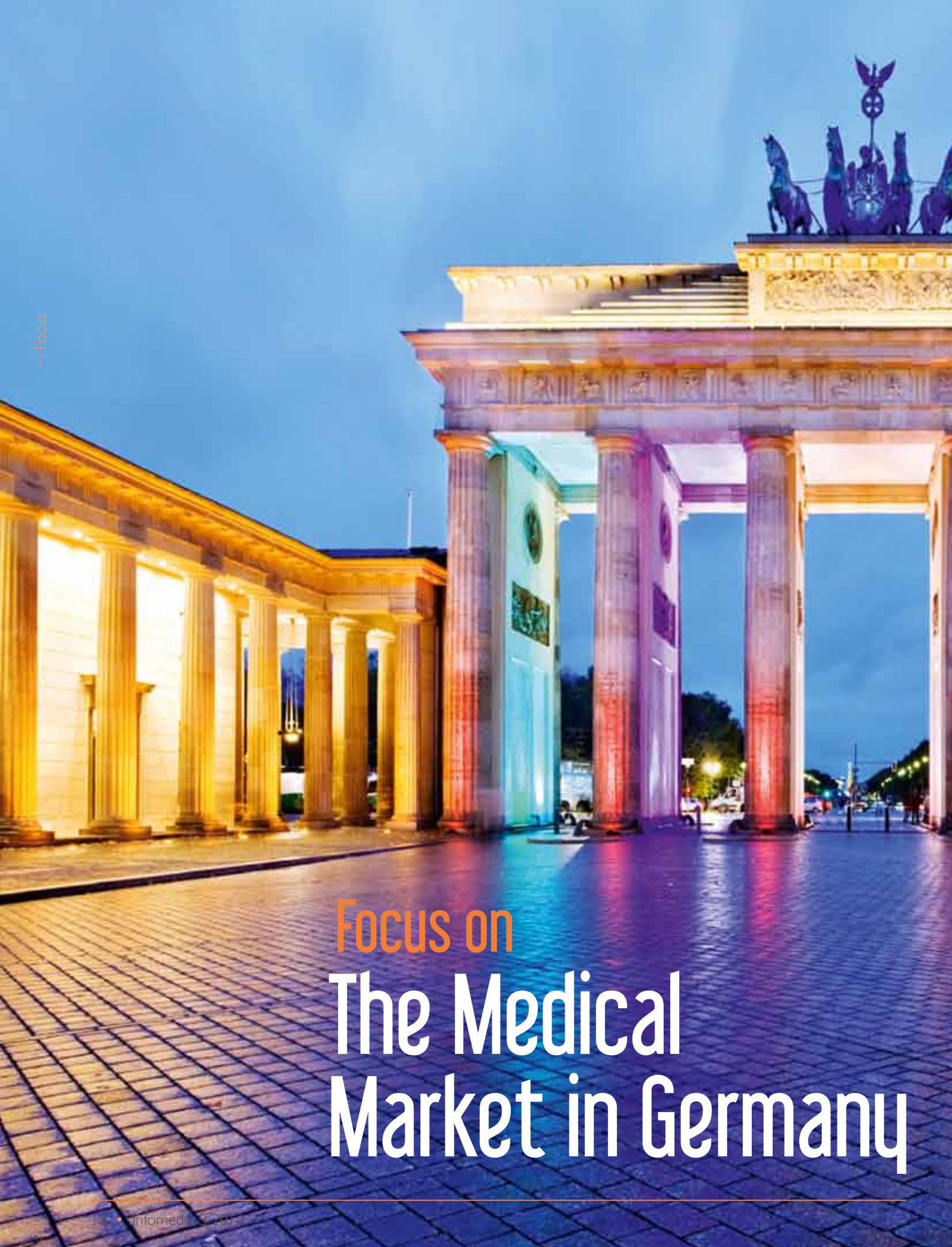
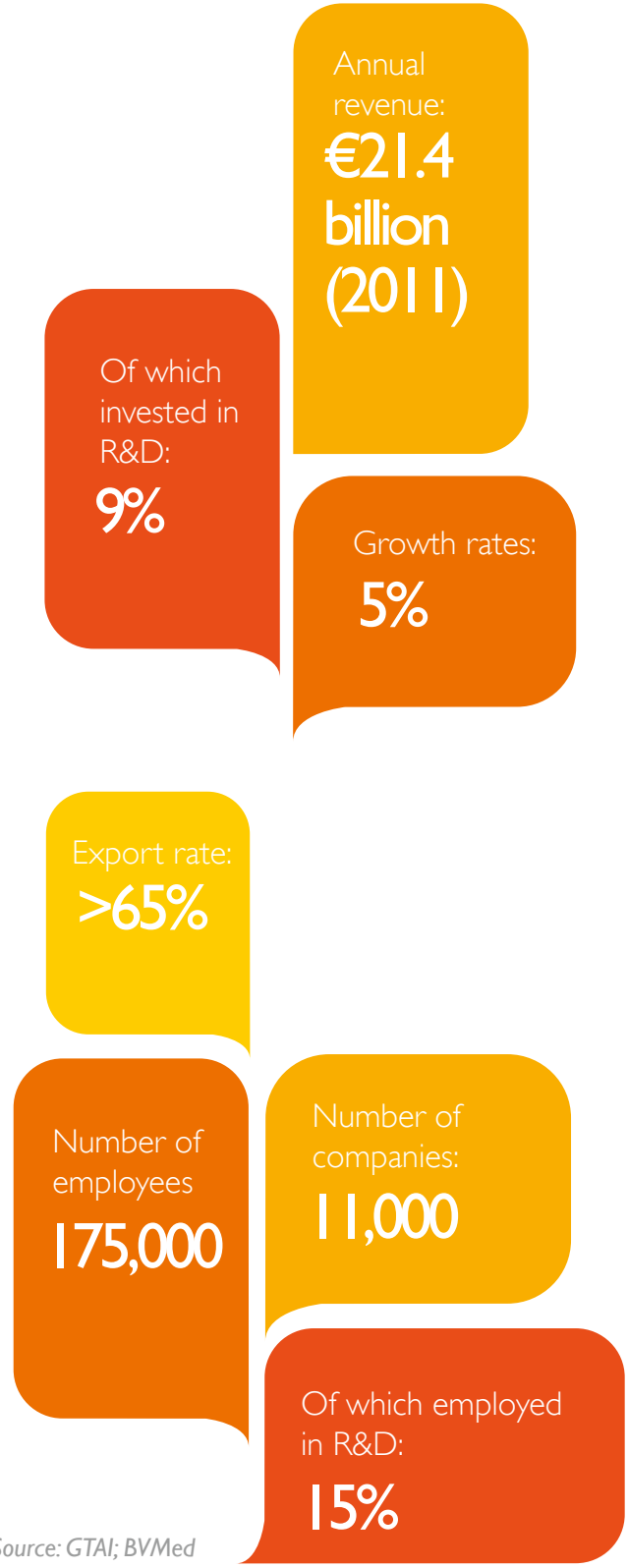


Focus on
The Medical Market in Germany

Figures about the medtech sector



Source: GTAI; BVMed

Market size

Germany is **Europe's largest market** for medical device manufacturing and the **second exporter of medical technology** worldwide with a share of **14.6% of the global trade** volume, second only to the United States and well ahead of Japan with its 5.5% share.

According to the ***"2012-03: Industry Report Medtech 2012"***, published by the German Medical Technology Association (BVMed), the **healthcare industry represents 11.6% of the German GDP totalling €278.3 billion in annual revenues,** a larger share than the automotive industry that is expected to be replaced by the healthcare sector as the country's flagship industry.

The agency Germany Trade and Invest reports that **healthcare expenditure on medical devices** (excluding investment goods and dental prostheses) is valued at around **€25 billion (around € 6.5 billion** coming from Statutory Health Insurance or SHI), so distributed:

- Medical devices (all cost bearers) **€ 2.8 billion**
- Other medical services **€ 1 billion**
- Dressings and bandages **€ billion**

	Value, 2010	Growth	Value, 2011	Growth
MedTech revenues	€20 bn	9.4%	€21.4 bn	6.9%
Foreign sales	€ 2.8 bn	12%	€ 4.2 bn	10.6%

The "BVMed Report September 2012" estimates **that total revenue of manufacturing** medical technology companies in Germany increased **by 6.9% to €21.4 billion in 2011,** but domestic revenue registered a mere **0.4% growth** in the same period, reaching **€7.2 billion.**

Germany is an internationally recognized manufacturer as well as Europe's leading business location for medical technology.

Profile of the industry

The Annual Report of the BVMed ***"Medical Technology Trends"*** highlights Germany's role as an internationally recognized manufacturer as well as Europe's leading business location for medical technology. The industry is dominated by small and medium-sized enterprises (with less than 250 employees) that account for 95% of the total, with an average of 78 employees per company compared to the general average of 130 employee per company in the German industry. The medical technology industry achieved to maintain its competitive edge despite the international recession, mainly because of the flexible and innovation oriented structure that helps the industry keep the pace with technological developments and new applications and devices that meet evolving market demands.

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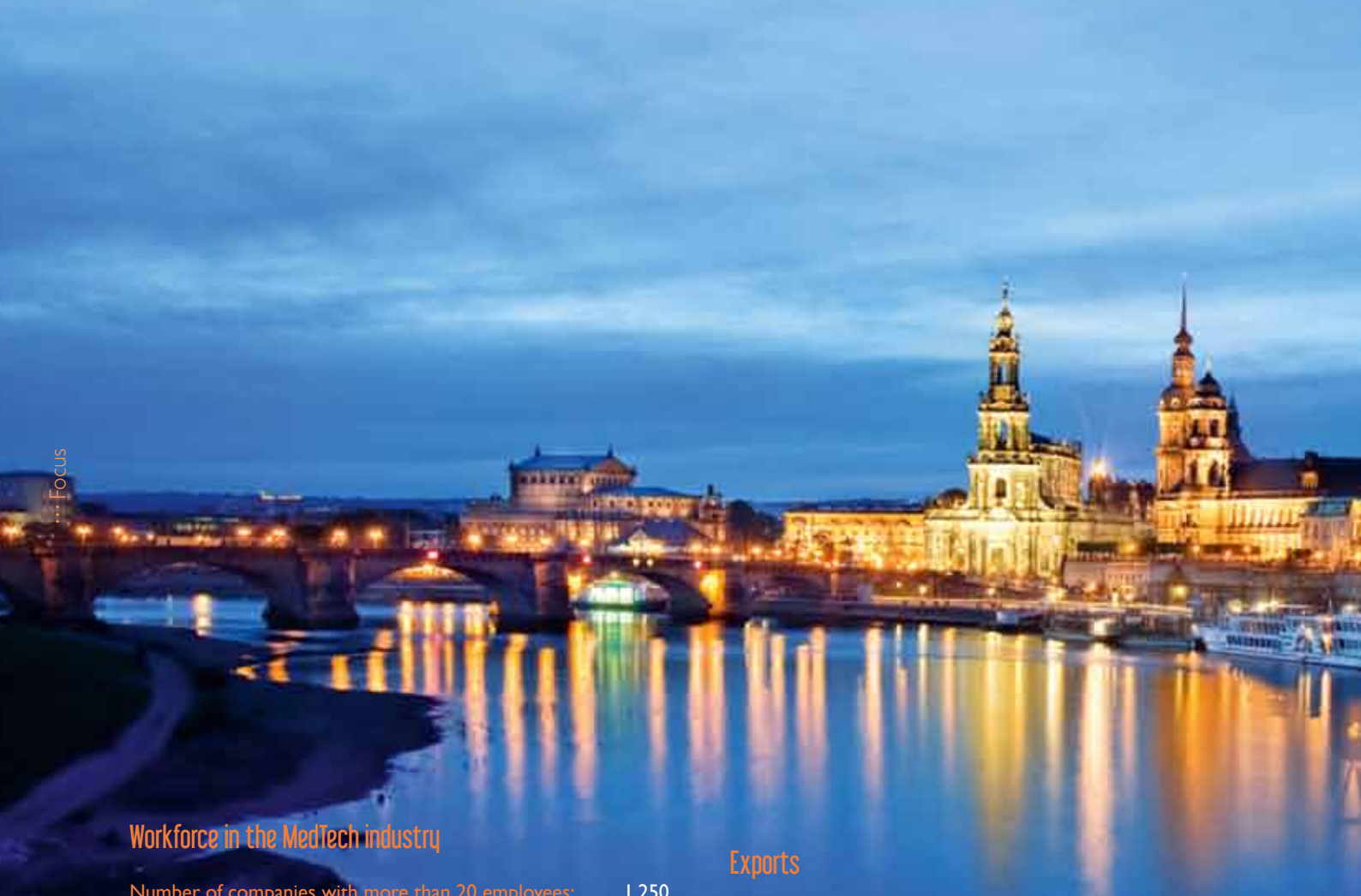

Workforce in the MedTech industry

Number of companies with more than 20 employees:	1,250
Number of employees:	100,000
Number of companies with less than 20 employees:	10,000
Number of employees:	75,000

As a whole, the healthcare industry is the largest employer in Germany with 5.4 million employees. The MedTech industry sector employs about 175,000 people in over 11,000 companies, and further 29,000 employees work in the retail sector for medical and orthopaedic goods. 15% of the employees work in research and development, with an upward trend.

In contrast to other manufacturing sectors where employment levels have declined over the past decade, in the period 2000 - 2008 the medical technology sector has seen a 12% increase in the number of its employees. According to the German Federal Ministry of Economics, 2 million people more will be working in the healthcare industry by 2030. Although 97% of all medical technology firms in Germany employ less than 500 people, large companies with more than 500 employees account for about 60% of the total turnover, while companies with less than 50 employees account for 9% of total turnover and 15% of the sector's employees.

The main medtech clusters are located in southern Germany, primarily in the federal states of Baden-Württemberg and Bavaria, that are home to about 350 companies. These two federal states alone account for more than half of the total turnover in the sector. Moreover, about a quarter of companies are based in the federal states of Hessen, Schleswig-Holstein, North Rhine-Westphalia and Berlin. These federal states have been able to gain their own international reputation as highly specialized locations in different sub-branches of the medical technology sector.

Exports

Exports made up the largest share of revenue, growing by 12% to ☐2.8 billion. Currently, about two-thirds of medical sales revenues are generated by exports (66% in 2011), a marked increase from the 40% averaged in the 1990s.

The largest single export market are the United States, with about 20% market share, while the most important regional market is represented by EU countries, accounting for about 40% of all sales. However, while exports towards the US grew by 13% in 2011, the areas towards which the strongest export growth was registered were Asia, with 17% share (increased by 26% year-on-year), followed by Middle and South America with 4% (increased by 28%) and extra-EU European countries. According to BVMed, German companies are well positioned on the international market thanks to the excellent reputation of the "Made in Germany" label, but also foreign companies are attracted to Germany as a central location for their operational base in the European market.

Competitive advantages

In her article *"What is Germany's Secret? How the World Can Learn from a Thriving Medtech Industry"*, published on Medical Device and Diagnostic Industry, Yvonne Klöpping from European Medical Device Technology outlines the main factors accountable for the good performance of German medical manufacturing industry despite the global financial turmoil:

• Ideal conditions for bringing new medical products and processes to market: large number of well-educated doctors, researchers, and engineers, high standard of clinical research, knowledge pool from university hospitals and research centres.

• Proximity to leading machine and packaging manufacturers, high quality and technical standards and dependable delivery service.

• Long established small- and medium-sized clusters of firms, which often specialize in niche areas of manufacturing, enjoying supportive funding mechanisms and networking possibilities with research institutes to develop new products.

• A favourable position in the heart of Europe, close to the most important European markets, with well-functioning infrastructure and transport connection, and a high security of supply.

• Overall corporate tax burden at 22.8 - 30%.

• Shorter time needed to bring medical devices to market compared to other important markets such as the US.

The latter point is a subject of debate between the FDA and US industry players, as they complain about the longer time and higher costs required to launch a product in their home market compared to Europe. On average, a device can enter the European market up to three years earlier, with significantly lower costs, although some justify the longer times and higher costs related to FDA approval with a more stringent regulatory environment aimed to prevent unsafe devices from entering the market. Germany is, however, in an excellent position to profit from the comparatively faster market access offered by the EU regulatory system.

Innovation is the engine of growth

Germany enjoys a long established R&D tradition that has been one of the main growth drivers for the MedTech industry, and still continues to ensure German products an excellent reputation worldwide. Some figures confirm it: as reported in the paper ***"Germany: Partner of the World"*** published by the Federal Ministry of Education and Research, according to the specific subject area in the field of medical technology, **between 5 and 20% of all scientific publications worldwide are generated in Germany.** In 2009, Germany had almost 20% (17,200) of the 134,542 patent applications registered at the European Patent Office, being second only to the USA in terms of the number of international patents in medical technology and by far Europe's strongest location for innovation in medical technology.

The leading position in European research environment and the availability of **qualified personnel** and good infrastructure boosts the German medtech industry and was among the main drivers for its average 7% annual growth, in spite of the deteriorating economic conditions worldwide.

Germany is an internationally recognized manufacturer as well as Europe's leading business location for medical technology.

Innovation is a must for a cutting-edge medical technology industry, but it especially makes the difference when it comes to overcoming periods of crisis by maintaining a competitive advantage in bringing to market new solutions in response to the challenge of reducing healthcare costs while at the same time improving the quality of care delivered to patients. In Germany, the sector benefits from an advanced R&D environment that remains a main focus for medical technology **manufacturers, who invest about 9% of their revenue in research and innovation activities.**

As a result, around one third of their sales are from devices that are less than three years old, accounting for the rapid introduction of innovative products into the market.

The close cooperation between R&D institutes and equipment manufacturers, qualified workforce with good engineering skills and the availability of in-house R&D facilities are all factors contributing to keep Germany at the forefront of the international research environment. Moreover, **financial support to R&D projects** is an important component of the country's economic policy, with incentives such as grants, interest-reduced loans, and special partnership programs available to all investors, whether they are from Germany or not.

The German Medical Technology Alliance highlights a particularly useful measure, **the Medical Technology Innovation Competition,** that funds selected research ideas to benefit especially small and medium-sized companies, often faced with financing problems due to long development processes of sometimes over a decade. The competition, held every year since 1999, gives researchers the opportunity to realize unusual and innovative ideas for medical technology products. The Federal Ministry for Education and Research (BMBF) allocates an annual □0 million under the funding measure. Since 2006, the competition has consisted of two modules: in the "basis" module, funding of up to □300,000 is provided for key experiments that demonstrate the feasibility of **creative ideas for development.** Once they have proved successful, the "transfer" competition module provides funding of up to □.5 million for research and development projects in which industrial enterprises are directly involved. By funding both these two modules, the BMBF is implementing the High-Tech Strategy to find solutions to crucial problems in medicine. To date, **1,093 applications have been submitted,** and 112 winners have been selected. The BMBF presented the award for innovative medical technology for the twelfth time in October 2010. There have been 15 winners so far.

In 2006 the BMBF has also started the initiative ***"Research in Germany – Land of Ideas",*** involving German research institutes, universities and enterprises that conduct R&D. Under this brand several German organisations, such as the International Bureau of the BMBF, the Alexander von Humboldt Foundation, the German Academic Exchange Service, the German Research Foundation and the Fraunhofer-Gesellschaft present German innovation and research in key international markets, with the aim of strengthening and expanding R&D collaboration between Germany and international partners. To better serve the purpose, the ***"Research in Germany"*** portal (www.research-in-germany.de) was created to inform researchers and scientists about research in Germany, provide an overview of the research and funding opportunities, deliver the latest science and research news from Germany and upcoming events and provide practical information to foreign scientists and researchers interested in collaborating with German research organisations or in a research stay in Germany.

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Within this framework, the special campaign ***"Germany – Partner for Medical Technology"*** was launched at the 2011 edition of Medica trade show in Düsseldorf, focusing on research in the field of medical technology from 2011 to 2013. As the medtech industry is particularly reliant on research and interdisciplinary contacts, though this initiative the government supports clusters made up of universities, research institutes, clinics, SMEs and large companies with the aim of initiating more mutually beneficial R&D collaborations between German and foreign research institutions and companies. One example is the Medical Valley European Metropolitan Region Nuremberg (EMN) in northern Bavaria, one of the most active medical technology clusters worldwide.

Key sectors for innovation

Within the context of the "Medical Technology" campaign the Federal Ministry of Education and Research identified six core fields of innovation that promise to expand significantly in the next future:

Imaging techniques: New methods such as positron emission tomography (PET) and single photon emission tomography (SPECT) are gaining importance. Imaging procedures enjoy financial supporting measures from the government, and the BMBF supported the development of a new type of facility at Research Centre Jülich, to combine magnetic resonance tomography with the positron emission tomography (PET) in a hybrid imaging process. Recently, researchers at the centre have developed a FET-PET method for diagnosis of brain metastases, that allows to ascertain after radiotherapy whether the treatment has been successful or if any new brain metastases have formed in the meantime, without any operation or tissue sampling.

Prosthetics and implants: Innovation is largely carried out by small and medium-sized companies based on interdisciplinary cooperation with researchers on material and biosciences.

Telemedicine: Key innovative sectors include electronic patient records, telemonitoring, expert systems, ambient assisted living, and virtual reality in medicine.

Surgical and interventional systems in medicine: Particularly innovative subareas include minimally invasive surgery, endoluminal interventions, techniques for ambulatory surgery robotics and navigation in surgery, surgical instruments, intensive medicine, interoperable devices and systems. The sector has a strong industrial base, primarily in the small and medium-sized family-owned company sector.

In-vitro diagnostics: Important innovative subareas include lab-on-chip technology, molecular diagnostics, immunodiagnostics, decentralized diagnostics, and individualized medicine.

Cell and Tissue Engineering

Moreover, innovative **individual approaches in medical technology** are being supported, such as the research collaboration on retina implants, an electronic retina prosthesis for patients with retinitis pigmentosa which is to replace the function of the degenerated retina and restore limited sight to patients. Four thematically focused working groups at twelve universities and non-university research institutes are currently collaborating on this national project.

Some of the R&D clusters and players involved in the ***"Medical Technologies"*** campaign, as listed in the official website of the project, include:

Auditory Valley

The R&D cluster Auditory Valley combines comprehensive knowledge and technologies for audio systems, hearing aids, and cochlear implants. The focus is on integrating hearing aid technology in more widely spread consumer electronics to help people benefit of hearing aids earlier.

BioNanoMedTech

The BioNanoMedTech competence network for biomolecular, regenerative methods and nanobiotechnology in medical engineering promotes the interlocking of nanobiotechnology with the regenerative medicine and in-vitro diagnostics along the entire value chain of regenerative medical engineering from basic research to clinical practice to the medical product. Partners from science such as international scientists, young scientists, and German researchers abroad as well as economy players are involved.

Plasma Medicine

This young medical discipline has emerged from the cooperation of physicians, physicists, and biologists, holding potentials for applications in the fields of wound healing, dentistry (peri-implantitis), dermatology (psoriasis, athlete's foot), implant medicine, and cosmetics (skin rejuvenation, microabrasion). A consortium of research institutes and medical engineering companies is intended to cooperate at an international level to raise awareness about plasma medicine and involve experts for further research.

3-D Imaging in Medicine

The Friedrich-Alexander University (FAU) with its spin-offs and links to Siemens Healthcare, Fraunhofer IIS and about 50 companies in the Metropolitan Region is at the heart of this campaign aiming at scientific exchange, integrating international competence in medical engineering and establishing international graduate cooperation in the area of Erlangen by conducting workshops abroad.

MOIN Molecular Imaging Network

MOIN Molecular Imaging Network is a preclinical imaging centre equipped with state-of-the-art imaging devices like magnetic resonance, computer tomography, sonography and optical processes for in-vivo imaging, focusing on developing new, innovative diagnostic and therapeutic procedures for detection and treatment of oncological, inflammatory and neurological processes.

"Labor der Zukunft"

This cluster of applied research centres and industrial companies led by Fraunhofer IBMT aims at developing, producing and promoting future (bio-)medical laboratory technology by integrating various fields of innovation like medical imaging for diagnostics, telemedicine for control, monitoring, and remote diagnostics, surgery and interventional systems, e.g. mobile operating theatres, voice and gesture controlled IT, robust and miniaturised in-vitro diagnostics systems, cell and tissue technologies like automated cell culture and biobanking.

German Medical Imaging In Motion (GMIM)

The consortium focuses on international marketing measures relating to medical imaging and image processing. The core of this campaign is the Mobile Interactive Cube, a mobile booth to be displayed at different locations in North America and Japan. The booth unites innovative topics of the members of the consortium both in the fields of preclinical, research-oriented imaging, like, for example, multimodal imaging, and clinical imaging and image processing.

Quantitative Imaging in Oncology (QUINO)

A competence network consisting of the German Cancer Research Center (DKFZ), the University Hospital of Heidelberg and the medium-sized companies CHILI Radiology GmbH and Mint Medical GmbH develops new procedures in medical image analysis through the open-source platform MITK (Medical Imaging Interaction Toolkit, www.mitk.org) covering the entire patient-centred care performed by medical engineering with special focus on cancer (oncology).

The innovation climate as perceived by the industry

According to the First Survey on the Medtech Innovation Climate conducted by the German Medical Technology Association (BVMed) on a total of 77 companies (cardiology 60%, neurology 43%, orthopaedics 40%, oncology 39%, diagnostics 31% and surgery 26%), Germany was rated 6.2 on a scale from 0 to 10.

The companies outlined what they believe are the main drivers of innovation in Germany:

1. Well-qualified medical technology scientists and engineers (78%)
2. High standard of patient care (56%)
3. Swift regulatory approval (51%)
4. Well-trained doctors (47%)
5. High standard of clinical research (44%)

Only 8% named availability of sufficient capital for innovation financing (start-up financing, venture capital).

However, some critical points remain:

1. Excessively bureaucratic procedures (68%)
2. Anti innovation policies of health insurers (66%)
3. Low reimbursement prices (53%)
4. Uncertainty about future evaluation of medical products (42 %)

Almost all industry players recognized the need to take practical initiatives for reducing bureaucracy and shifting the focus of statutory health insurance away from price, towards quality.

Highlight: the German orthopaedic industry

- Size: 74 companies (with 50 employees or more) manufacturing orthopaedic products; 11 plants for the production of wheelchairs and vehicles for handicapped people.
- Number of employees: around 15,000
- Turnover: about ☐2.2 billion
- Total market size: ☐4.32 billion, with ☐3.45 billion generated by the country's 1,873 prosthetists and 2,491 medical suppliers.
- Health spending on medical aids (2008): ☐2.8 billion

Sources:

German Medical Technology Alliance - http://www.gmta.de

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Outlook on Nigeria

Facts & Figures

Source: NSO

The Federal Republic of Nigeria lies in Western Central Africa, on the Gulf of Guinea. It became a democracy in 1999 and it is Africa's biggest oil producer and most populous country with 160 million inhabitants and more than 250 ethnic groups. The northern part of the country is mainly populated by Muslims while Christians live predominantly in the South-Eastern states. Part of the population still belongs to traditional African religions. **Poverty is a pressing issue as it affects 70% of population,** 37.5% of which is categorized as living in extreme poverty. Security concerns arise from ethnic and religious tensions as well as separatist claims often bursting into violent conflicts and attacks.

Economy

According to the Economist newspaper, Nigeria's economy may become Africa's biggest by 2016.
The latest ***"Economic Outlook"*** released by the Nigerian Statistical Office shows **encouraging GDP figures:**

- after several years of sustained growth at 7-8%, the country's GDP is projected to grow by
- 6.5% in 2012, a decline from 7.6% recorded in 2011
- over 7% average growth rate in the period 2013-2015

However, the oil sector suffers **the lack of adequate infrastructure and refining industry** and it is subject to corruption and mismanagement; it also arises contestations among activists claiming a greater share in revenues from this sector that generates wealth only for a small part of the local population. **Inflation** is another problematic issue, even though the average rate for 2011 decreased at 10.9% from 13.8% in 2010. The projected inflation rate in 2012 will be 13.5%, and it is expected to remain around 12% until 2015.
Nigeria's government has set the ambitious goal to become one of the **top 20 economies** of the world by the year **2020** and it is therefore revising its policies to diversify the economy and ensure more inclusive growth.

In an interview at the 2012 IMF World Bank Spring Meeting in Washington D.C. Mrs Ngozi Okonjo-Iweala, Nigeria's Finance Minister, claimed that some steps in this direction have already been done with higher **investment in agriculture and infrastructure** development, and support programs for young entrepreneurs.

The Minister stated that current government focus is on investing in sectors that are **job-creating.** As the oil and mining sectors are more capital-intensive and do not provide enough employment to benefit large shares of the population, agriculture and manufacturing are the two sectors that can better serve this purpose.

According to the Manufacturers Association of Nigeria, **manufacturing contributes less than 5% to the country's GDP and industrial capacity is between 35% and 40%,** but the sector is growing at annual 10%, despite challenges incluse interruptions in power supply, high financing costs, a complicated import tariff regime and poor transport infrastructure.

The strongest segments are food and beverage (22%), cement, textiles and household chemicals, while most electrical consumables are imported from Asia. The manufacturing sector is mainly concentrated in greater Lagos, while heavy industry complexes and chemical, pharmaceutical and engineering conglomerates are located in South-Central and South-East Nigeria.

Moreover, several tertiary sectors are developing: **telecommunication registered 34.7% growth in 2011,** while wholesale and retail, building and construction, hotel and restaurants and real estate all grew between 10-12%. Reducing the dependency on oil and developing job-creating sectors is therefore crucial to make growth more inclusive by extending it to rural areas that experience significantly higher poverty rates than the cities.

Investment incentives

Mineral resources and agricultural products are the traditional sectors of investment in Nigeria, but leather and textile industry are also expanding. As a result of debt reduction agreements, Nigeria was the first African country to fully pay off a debt of about $30 billion.

Although high import tariffs and import bans were introduced due to protetionistic, import-substitution policies, **Nigeria is relieving taxes on several import products** while at the same time trying to encourage local source of raw materials to be processed in the country and re-exported.

Country Overview

The Federal Republic of **Nigeria** lies in **Western Central Africa**, on the Gulf of Guinea.

Africa's
- **biggest oil producer**
- **most populous country**

160 million inhabitants **&** **more** than **250** ethnic groups.

1999
It became a democracy

Nigeria is one of the world's richest countries in **natural resources:**

12th largest oil producer

8th largest oil exporter in the world

7th largest natural gas reserve

The Nigerian government is adopting **measures aimed at attracting foreign investment** into the country. As reported by the Ministry of Foreign Affairs, the Companies Income Tax Act has been amended to the purpose and the current **income tax rate** in all sectors, except for petroleum, is **30%.**

Other tax measures include the **"Pioneer status"** tax holiday, currently granted to **69 pioneer industries** including medical manufacturing, anywhere in the Federation, and seven-year tax holiday for industries located in economically disadvantaged Local Government Area. In particular, a pioneer industry located in one of such Areas has 100% tax holiday for seven years plus additional capital depreciation allowances.

Moreover, investments in R&D are encouraged as **120% of R&D expenses** are **tax deductible** if carried out in Nigeria related to the business generating the revenue. Since the Nigerian Investment Promotion Commission Act was approved in 1995, foreign investors may own 100% shares in any company and repatriate their profits and dividends net of taxes through an authorized dealer in freely convertible currency.

Double taxation agreements with a number of countries allow tax payable in Nigeria on profits of a Nigeria company being remitted into the country to be reduced by the amount of "foreign tax" paid abroad. Nigeria has DTA with UK, France, Netherlands, Belgium, Pakistan, Canada, Czech Republic, Philippines and Romania; **negotiations are in progress with other countries** like Turkey, Russia, India, and Korea. Companies investing in Nigeria are obliged to register with the Corporate Affairs Commission which has recently established regional offices.

Healthcare

According to a report released last year by the UN Industrial Development Organization, Nigeria's health indicators are still too poor to meet most of the targets for the Millennium Development Goals (MDGs) set for 2015.

The Nigerian online magazine Punch reports that **the nation's healthcare sector accounts on average for about 5% of GDP, 65% of which comes from private spending,** although prepaid health schemes through health maintenance organisations are increasing.

The main challenges in Nigeria's healthcare system include:

- **fragmented health service delivery**
- **inadequate and inefficient financing**
- **weak health infrastructure**
- **inefficient distribution of the health workforce**
- **lack of management and poor coordination amongst key players**
- **low motivation among health workers**
- **frequent stock-outs of essential medicines and supplies**

Despite the existence of numerous primary health centres and a relatively high level of investment in health, **good-quality basic health services are not easily available to poor people as their distribution,** as well as the referral system, are insufficient. The public sector still experiences poor service conditions, over-used facilities and low funding, although it attracts most of the country's health quality professionals who also engage in private practices, and is being paid increasing attention by the government. However, health maintenance organisations (HMO) have contributed to improve the level of access to healthcare mostly among the working class.

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The healthcare system is dominated by the public sector but the private sector, though smaller, is expanding especially in the areas of specialized hi-tech services provided to the middle and upper income class.

The Federal Government **is in charge of the Federal University Teaching** Hospitals while primary healthcare is under the responsibility of Local Government Authorities, who provide **basic care,** education and prevention, diagnosis and treatment for **most common diseases** in local healthcare centres or dispensaries. They refer complicated cases to secondary care centres such as comprehensive health centres and hospitals that treat minimal complex cases in medical, surgical, paediatric and obstetric care, while more complicated cases are referred to the tertiary or specialist hospital.

As reported in the paper ***"Infrastructural distribution of healthcare services in Nigeria: An overview"*** (Journal of Geography and Regional Planning, 2009) **the comprehensive health centres are often privately owned** (such as Gold Cross Ikoyi in Lagos, Victory Hospital, Ijebu-Igbo) **whereas general hospitals are owned and funded by government** (such as Ijebu-Ode, Ikeja, Ilesa, Oluyoro in Ibadan, Abeokuta). Primary health centres are mainly associated with rural and semi-urban environments or mixed population, while general hospitals are located in the state capitals and a few other big towns.

A tertiary or specialist/teaching hospital handles complex health cases either as referrals from general hospitals or on direct admission to its own. Teaching hospitals also conduct research and are often university-based (such as Lagos University Teaching Hospital, [LUTH], University College Hospital (UCH), Ibadan, The National Orthopedic Hospital, Igbobi Yaba, The Psychiatric Hospitals in Aro, Abeokuta and Yaba in Lagos, National Hospital in Abuja, University of Nigeria Teaching Hospital, Enugu, etc.). **Tertiary hospitals are controlled and funded by the Federal Government and by some states that have and run state universities, so they are mainly urban-based.** As they need to be accredited for teaching purposes, such hospitals must meet international standards in terms of equipment, specialists and auxiliary staff.

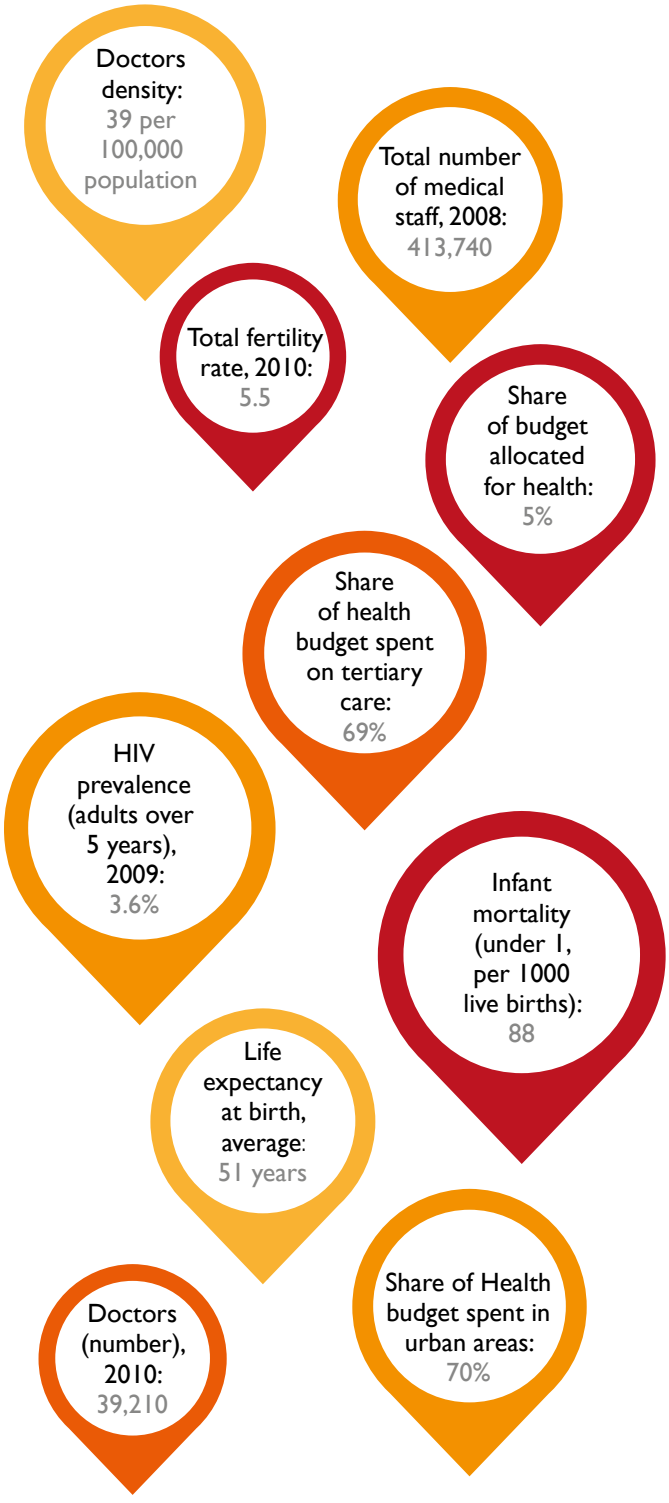
Dr. Olumuyiwa Odusote, Chairman of the Lagos State Medical Guild, recently recognized that **70% of healthcare services in Nigeria are provided by private hospitals,** and therefore not accessible to many Nigerians who cannot afford to pay for them, while public health institutions are under-staffed and ill-equipped to meet demand. This in turn reflects need to increase implementation of the National Health Insurance Scheme, which was introduced in 2006 to address the issue of access to healthcare, but only benefits about 10% of the population.

Maternal and child health are a particular concern due to the **high rate of infant mortality** and the difficult access to proper healthcare for the majority of population also accounts for **low life expectancy** still registered in the country. Moreover, the burden of diseases such as **malaria** and **HIV** is also high.

Other categories of healthcare services that have been given **high priority** include non-curative components of primary health care, such as sanitation health education, national preventive campaigns against childhood diseases and free compulsory **immunization programs.**

The main problem of the Nigeria's health system is the **uneven distribution of healthcare services,** favouring the urban areas where the majority of educated Nigerians, government functionaries and richest groups live, while **rural population** remain largely underserved.

According to the World Bank **that is allocating $150 million for the Nigeria State Health Investment Project,** the country's government has started addressing the issues that prevent poor people from accessing basic healthcare. Some Nigerian states such as Adamawa, Nasarawa and Ondo are introducing changes at the health centre level based on so called **"Results-Based Financing",** a performance-based incentive approach, currently focused on maternal and child health.



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The **World Bank has destined $21.5 million** to fund, among other things, an impact evaluation to test the success of the approach in the three pilot states and its applicability to the other states of Nigeria.

The role of the private sector

The limited ability of the public health system to meet the demand for healthcare for the whole Nigerian population implies as a possible solution an increased role played by the private sector acting as a partner in providing quality health services, especially to rural, lower-income, and remote populations that are currently finding more barriers to access them. A study conducted by USAID on the potential outcome of a greater engagement of the private sector in Nigeria's health system shows some interesting figures on this topic.

Number of private medical professionals
Doctors: 20,000
(roughly the same as in public sector)
Nursing staff: 60,517 (about 50% of public)
Laboratory staff: 8,456 (42% of public)
Pharmaceutical staff: 2,202 (16% of public)
Total private medical staff: 111,587
(288,061 public)
Source: USAID

This means that a **urban resident** has access to nearly three times as many public sector doctors and four times as many private sector doctors compared with a rural resident; moreover, he or she also has access to twice as many nurses/midwives overall. **Rural residents** have therefore access to much fewer numbers of doctors and nursing staff compared to urban residents across both the public and private health sectors.

According to the study, **private health facilities attract new graduates** (doctors as well as nurses) at a higher rate than public health facilities. Despite being concentrated in few geographic zones, and lower in number compared to the public sector, private facilities employ more than their proportionate share of Nigeria's doctors.

USAID estimates that by assuming current entry/exit rates, the stock of private sector nursing staff will be almost constant in the future, while the **total number of private of doctors will grow** over time, potentially widening the gap with the public sector.

Telemedicine is seen as a promising instrument to favour rural and semi-urban communities that lack access to healthcare facilities. As part of Nigeria's agenda for universal access to primary healthcare services that aims at providing access to a form of healthcare service within 15 kilometres to every Nigerian by 2015, technology infrastructure development, capacity building and training for healthcare personnel are all priority areas for health investment.

The **Society for Telemedicine and e-Health** in Nigeria (SFTeHIN), is **encouraging adoption of telemedicine by hospitals, public agencies and private healthcare operators** including social entrepreneurs who work in rural communities.

In May 2007, the Nigerian Communications Commission (NCC) issued third generation (3G) licenses to four telecommunications companies to pave the way for high speed voice, data and video transmission networks.

Supply of medical equipment

Most of **medical equipment** and pharmaceuticals in Nigeria **need to be imported** as local production is limited to peripheral items such as hospital beds and gurneys due to lack of infrastructure and know-how to produce more sophisticated medical equipment.

As malaria is one of the most common diseases especially among young children and pregnant women, **equipment for preventing and treating malaria cases is particularly needed.**

According to a market insight by Global Impact Consulting, demand for medical equipment derives both from public and private sector which also account for much of the imports and informal exports to West Africa. **The private sector is also the main purchaser of refurbished and used medical equipment.** The same report highlights the opportunities for professional training and environmental services to address the lack of specialist expertise in many specialized fields and the current shortage of cutting-edge technology application in most healthcare institutions in Nigeria.

Another market analysis from Frost & Sullivan estimates **that revitalisation and new hospitals' market, valued at $125.4 million in 2010, is going to reach $149 million by 2017.** The emerging Nigerian middle class is said to be adopting more Western lifestyles impacting on the increase of non-communicable diseases and leading the richest part of the population to seek private care in order to access better quality and avoid long waiting lists that are common in the public sector.

The **rising demand for specialist healthcare services** is driving the construction of new hospitals although the high costs due to the necessity to import most of the machinery and materials except for those that can be sourced locally. Moreover, power and water supply may be an issue.

Public-private partnerships are usually a good way to invest in the health sector as it expands available financing while improving efficiency and enhance quality of health services through more rapid investments in infrastructure and new medical technology, which in turn holds the potential to attract and retain more expertise and better performing staff. On the other hand, the **private sector may benefit from under-utilised government operating theatres, equipment, and buildings.**

A £50 million programme named Partnerships for Transforming Health Systems (PATHS) was initiated by the Nigerian government with the aim of improving the delivery and use of effective, affordable health services for common health problems that affect poor people in Nigeria. The aim is to boost the use of health facilities by around 25%, especially in rural areas, and also provide funding of pharmaceutical equipment.

The programme is funded by the UK Department for International Development (DFID) and managed by a consortium of five international institutions. PATHS is working in partnership both with the public and the private sector and it is currently being implemented in four states: Enugu, Jigawa, Kaduna and Kano.

"In Nigeria and other developing countries, sustainable access to healthcare and other socio-economic services and products can be accomplished through public-private partnerships, where the government delivers the minimum standard of services, products and or care, the private sector brings skills and core competencies, while donors and business bring funding and other resources. Such collaborations will be especially productive in promoting poverty alleviation through micro-finance, enhancing health through partnerships as has been the case with polio eradication and other child immunization efforts."

Foundation for Public-Private Partnerships, Nigeria

Some critical issues for the medical industry

- Import taxes and high competition requiring strong marketing and promotional efforts rise costs to industry players;
- Receivable days are more than payable days, increasing delays in payments from distributors;
- Although good earning potentials, cost-to-sale ratio at 3-year average were estimated at 53% in 2011, while operating and running cost are estimated at 39%;
- An estimated 40% market share for counterfeit drugs puts pressure on the pharmaceutical sector, with cheap drug import from China and India also affecting sales. However, the NAFDAC, Nigeria's National Agency for Food and Drug Administration and Control, is strengthened its activity for drug quality control and actively campaigning against the counterfeiting industry.

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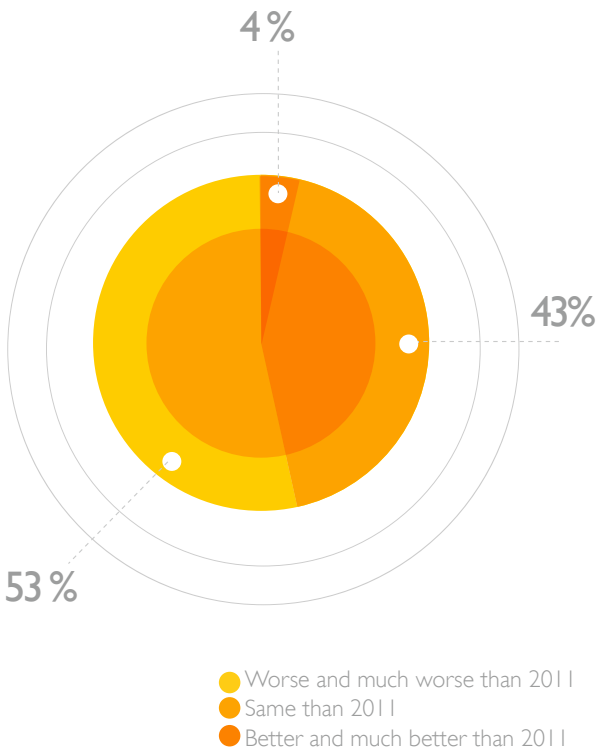
EU medical device industry:

Good mood in moderate times

A Simon-Kucher survey reveals that pricing pressure and the volatility of the current reimbursement situation in Europe are the industry's main concerns in 2012.

Bonn, May 22, 2012 – Driven by aggressive pricing from low-cost competitors and customer centralization, pricing pressure in the European medical device industry will continue in 2012. Short-term revenues and profits, however, are expected to increase by mid-single digits in spite of commercial key challenges such as funding uncertainties. These are the key findings of the MedTech Barometer 2012*, conducted by global strategy and marketing consultancy Simon-Kucher & Partners. The pricing experts asked about 80 top-level decision makers from the world's leading medical technology companies in all key subsectors including equipment, supplies, devices, diagnostics, and dental products about the commercial trends and challenges they face. 43 percent of respondents state that they expect the overall positive business climate in the medical device industry to continue in 2012.

Expected market prices



Prices in the European medical device industry are under pressure

Positive and stable business outlook

Despite obvious challenges, overall business expectations for the medical technology sector in Europe remain positive for 2012. The respondents across the different sectors (except diagnostics) expect their operations to grow by an average of +6 percent in revenue and +5 percent in profit. This is very much along the same lines of their 2011 expectations. In general, companies also plan to maintain stable average selling prices.

Price pressure and funding uncertainties worry experts

Constant price pressure coming from the provider side and from competitors are serious sources of concern. With 59 percent and 58 percent, these two topics rank among the top three commercial challenges of the industry and are even likely to gain importance in the future. Respondents claim that providers focusing too much on price and increasing procurement centralization are driving value out of the selling equation. The study also shows that price and commercial aggressiveness of current players are the main drivers of competitive dynamics, even less than the entry of new products or competitors.

However, for a clear majority of 66 percent, the main issue keeping industry leaders awake at night concerns reimbursement and funding. Several markets are closely scrutinizing public spending and tightening up funding levels. Moreover, approval requirements are expected to become more stringent which may have an impact on timelines. **"Overall we would have expected a darker mood for this year, but companies are probably betting on innovation to save the day,"** says report co-author Joerg Kruetten, Executive Vice President and head of Simon-Kucher's global medical technology competence center.

Innovation counters negative effects

The industry innovation rate is high and expected to continue its upward climb in the future. A significant 31 percent of company representatives participating in the survey state that the revenues of their employers were generated by the sales of products not older than three years. Two-thirds of these products were next-generation products that evolved from an already established technology; the other third were breakthrough innovations, i.e. technologies that introduced a paradigm shift in healthcare. "Our results show that innovations will remain the industry's fuel. Revenue generated by new products is likely to swell significantly in the next three to five years," predicts Carlos Meca, Senior Consultant at Simon-Kucher and co-author of the report. Still, there are major hurdles to overcome in terms of market access. Effective portfolio management, i.e. how to successfully combine new vs. old-generation products in the market, will be just as essential as achieving and sustaining price premiums for the improved products. Moreover, working together early and closely enough with reimbursement authorities as well as local budget holders will be crucial to ensure companies' market positions.

**About the MedTech Barometer 2012*

The MedTech Barometer 2012 reveals commercial trends and challenges in the medical technology industry. The approx. 80 survey respondents come from a pool of C-level executives, regional and BU heads, and senior functional executives representing all key sub-sectors including equipment, supplies, devices, diagnostics and dental.
The management summary is available upon request.

Study authors

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Spain Needs to Deliver on Reforms to Stabilize Economy

• **Key goals:** make the economy more competitive to boost growth, clean up the financial sector, put public finances on a sustainable footing
• **Labor reforms should aim to put more people back to work**
• **IMF will monitor financial assistance to Spain's banks**

The Spanish government has passed a number of reforms to help the economy and financial system as the ongoing crisis in Europe means higher borrowing costs for the country. On the heels of the IMF's latest annual check-up of Spain's economy, James Daniel, IMF mission chief for Spain, sits down for an interview with IMF Survey online to discuss the challenges of reforming the country's economy and explain the IMF's policy recommendations.

• IMF Survey online: **What is the best way for Spain to balance austerity measures and increase economic growth?**

Daniel: The government seeks to strike a balance between the need to cut back the deficit and boost economic growth in three ways.
First, by making sure the measures to reduce the fiscal deficit are as growth-friendly as possible. One example of such measures would be increasing the revenue derived from the value-added tax, rather than cutting productive spending. Raising the value-added tax has a less negative effect on growth than cutting spending; especially spending that has the potential to help growth. When compared to other countries in Europe, Spain raises less from the value added tax.
Second, the government is implementing reforms to make the economy more competitive, which will have a positive effect on growth. It should do more in this area. **And third, by making the financial system work better.** For example, the European loan will help clean up banks so they can lend more to healthy businesses rather than being stuck with loans to defunct real estate projects.

• IMF Survey online: **Why is unemployment so high in Spain, especially among young people, and what reforms are needed to address this problem?**

Daniel: This is a big issue for a number of reasons. **First and foremost, it's bad for human dignity and a large strain for families. It also has adverse economic implications:** it's bad for government revenues, it can lower potential growth going forward, and it's bad for the banks because people out of work can't afford to pay back their loans.
First, let me say that unemployment is unacceptably high in Spain, much higher than in other countries, especially for young people. **Unemployment has risen to almost 25 percent and for young people it is now over 50 percent, which is terrible.** Part of the reason is the bursting of the housing bubble, but that's only part of the story. Spain has always had high unemployment and there are other countries that have had housing bubbles burst that have not had such high unemployment, such as the United States, Ireland, and the United Kingdom.
As we have pointed out for many years, there are big problems in the way the Spanish labor market works or, rather, doesn't work. Especially the big divide between those with permanent and protected jobs and those, who are often young, with temporary jobs. This structure of the labor market means that when bad economic times hit, firms have to adjust by sacking temporary workers rather than by changing working conditions, including wages. This way of doing things disproportionately affects young workers. In the rest of the world they do a bit of both, hiring and firing, but also changing working conditions and adjusting wages. For example, temporary employment has fallen by a third since the beginning of the crisis, whereas permanent employment has only dropped by 6 percent.
Fixing this requires making the labor market more inclusive. **So the IMF is recommending two things for Spain: make sure more people are working; and give firms the confidence to hire, even if it means some people are working in a different way, under more flexible conditions, or for less pay.** We would like to see a more inclusive labor market rather than one divided between protected and unprotected workers; one that helps firms adjust to difficult times without having to let workers go.
In other countries wages go up and down, and employment doesn't move so much. Spain is the outlier. **We want firms to be able to agree with their workers about working conditions that reflect economic conditions, and not having to respond just by sacking people.**
The labor market reforms adopted by this government in February of this year and by previous governments go in this direction. Of course, these are very sensitive issues that affect society at large and are difficult to change. Indeed, we suggest it might be helpful to have a more cooperative approach that involves the government, the labor unions, and the employers whereby regaining competitiveness should be the overarching objective.

• IMF Survey online: **Financial markets don't appear convinced by the reforms already taken by the government—what more can they do to restore investor and market confidence?**

Daniel: **Spain's plans are good, it now needs to deliver.** The country has passed many reforms and made many commitments, and now the government needs to deliver on them so the results can be seen. For example, it's not enough to announce ambitious fiscal deficit targets, especially as in the past these targets were missed. The government now needs to hit these targets. Actually, it should be trying to surpass these targets, to generate good, not bad, surprises. The recent package of measures, which includes raising the value-added tax from 18 to 21 percent and the removal of the mortgage income tax deduction, is encouraging in this regard. These are measures well designed to minimize the drag on growth. **But the problems that Spain faces in the financial markets go beyond the country's borders, and speak to the design flaws in the eurozone.** European leaders need to complete the reforms they have announced and fix the flaws in the monetary union. Most immediately, for example, Europe could draw up a roadmap for transforming the European loan to the government into a direct recapitalization of banks by Europe's rescue fund, the European Stability Mechanism. Spain's role would be to demonstrate to its eurozone partners that the country is putting its own house in order.
Many of the reforms will take some time to bear fruit. Take the example of labor market reform; in the current difficult environment it's hard to see that employment will be created quickly, but we should be able to see the signs of it working. We would like to see evidence that firms are now using the new law, for example, to have more firm-level agreements, and to change working conditions so that they don't have to cut jobs. There are some tentative signs this could be happening.

Source:
Author: IMF- International Monetary Fund
Publication: IMF Survey Magazine
Website: www.imf.org

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Modest U.S. Recovery, but Europe is a Key Risk

- **U.S. economy expected to grow by 2 percent in 2012 as strains in Europe intensify**
- **Key challenge is to manage pace of deficit reduction without hurting economy**
- **Progress made but more efforts needed to increase resilience of U.S. financial system**

The **U.S economy continues to recover at a tepid pace,** while concerns about the euro area debt crisis and uncertainty over domestic fiscal plans are creating a challenging environment for the world's largest economy, the IMF said after wrapping up its annual review of the U.S. economy. An IMF team met with Treasury Secretary Timothy Geithner, Federal Reserve Chairman Ben Bernanke, and other senior U.S. officials to conduct the annual review.

"The United States remains vulnerable to contagion from an intensification of the euro area debt crisis, which would be transmitted mainly via a generalized increase in risk aversion and lower asset prices, as well as from trade channels" said IMF Managing Director Christine Lagarde during a press conference in Washington, D.C. On the domestic front, failure to reach an agreement on near-term tax and spending policies would trigger a severe "fiscal cliff" in 2013, threatening the recovery, she added.

The IMF expects U.S. growth to remain modest during the next two years, constrained by housing difficulties, the expiration of fiscal stimulus measures, and continued low global demand, particularly in Europe. **Growth is projected at 2 percent in 2012 and about 2 percent in 2013.** The main policy challenge is to use the limited policy space to support the recovery in the near term, while restoring medium-term fiscal sustainability and completing financial sector reforms. The crisis and ensuing recession significantly worsened the state of U.S. public finances and exposed vast gaps in the financial and regulatory frameworks, the IMF said.

Supporting the recovery

With inflation kept in check by the sizeable economic slack, and unemployment projected to decline only slowly, the IMF supports the Federal Reserve's intention to keep the monetary policy stance accommodative for an extended period. Should the outlook worsen, a number of tools could be used for further easing, including through additional purchases of mortgage-backed securities.

Removing distortions

The IMF stressed the need for more aggressive efforts to accelerate the resolution of the housing crisis. These include measures to facilitate the conversion of foreclosed properties into rental units and supporting access to refinancing on a larger scale. Another option would be to allow mortgages on principal residences to be modified in personal bankruptcy without secured creditors' consent ("cram-downs").
At the same time, the IMF said that measures are needed to reduce the risk that long-term unemployment could morph into higher structural unemployment and reduce potential output. Active labor market policies, such as training and support for job search, should therefore be adequately funded.

Regulation of the financial sector

Good progress has been made in reforming the U.S. financial system, but vulnerabilities remain, the IMF said.
Four specific areas were highlighted for further progress:

- **Regulation of the shadow banking system:** Given the size of the industry and prominence in short-term funding, strengthening regulation of Money Market Mutual Funds remains critical.
- **Volcker rule:** A ban on proprietary trading by banks should, in principle, reduce systemic risk.
- **Housing finance:** Measures to help the recovery of private securitization would ease mortgage market conditions.
- **Funding for regulatory agencies:** Adequate implementation of domestic and international reforms requires appropriate funding to the regulatory and supervisory agencies.

Global spillovers

As the world's largest economy, the policy actions of the U.S. have significant effects on global growth and stability. Striking the right balance between fiscal consolidation and economic policy support would benefit the rest of the world, as it would avoid the risk of a spike in U.S. interest rates and an abrupt decline in U.S. growth in 2013. Further progress in implementing financial reforms would also be globally beneficial and reduce the scope for regulatory arbitrage.

Source:
Author: IMF- International Monetary Fund
Publication: IMF Survey Magazine
Website: www.imf.org

Italian Medical Industry:
Special Insight on Imaging Diagnostics

General overview of the medical manufacturing industry

According to the latest figures reported by ASSOBIOMEDICA (the Italian association of biomedical manufacturers) there are about **700 medical manufacturers in Italy,** about **15%** of which are multinational companies mainly located in **northern regions (77%), followed by central (20%) and southern Italy (3-4%).**

13% of companies manufacture components for third parties.

About 90% of companies are small enterprises, and the sector as a whole employs **33,000 people.**

Italy was the 12th medical device exporter worldwide in 2010, for a total value of **US$246 billion,** with a reduced share in countries such as USA, Germany and China, whereas it enjoys a good market position in areas such as Africa and eastern Europe.

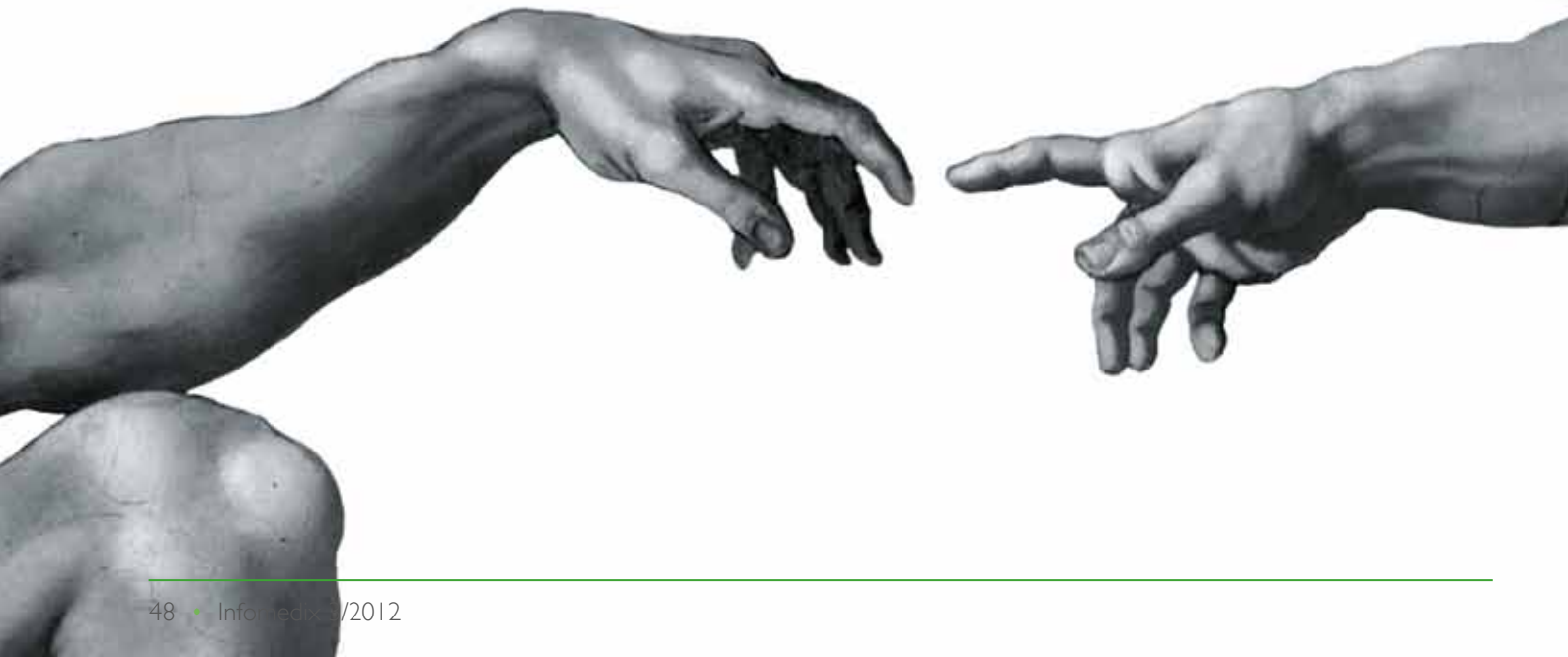
However, being also the **world's 9th medical device importer,** Italy's trade balance in this sector is negative.

Geographic distribution and main clusters - **The Italian regions where most of the medical manufacturers are based are Lombardy, Emilia- Romagna and Veneto, followed by Lazio and Tuscany.**

Provinces with the greatest concentration of companies are **Milan, Modena, Bologna, Padua, Rome and Florence.**

In particular, the **city of Mirandola** in the province of Modena hosts a specialized district where devices for dialisis, plasmapheresis, transfusion and infusion equipment are produced; i**t is the most important cluster in Italy accounting for 30% of sales.** Unfortunately, this area was recently hit by an earthquake that caused great damages to the local productive network.

1- Milan
2- Padua
3- Modena
4- Bologna
5- Florence
6- Rome



Italian public health system in figures (2011)

Share of public health expenditure on GDP: **7.1%**

Share of public expenditure on total health expenditure: **77.3%**

Nursing staff: about **311,000**

National health system personnel: **>812,000**

Total public health expenditure: **€ 111 billion**

Physicians: about **144,000**

- Total production **€ 36,800 million**
  - » Towards domestic market **€ 31,700 million**

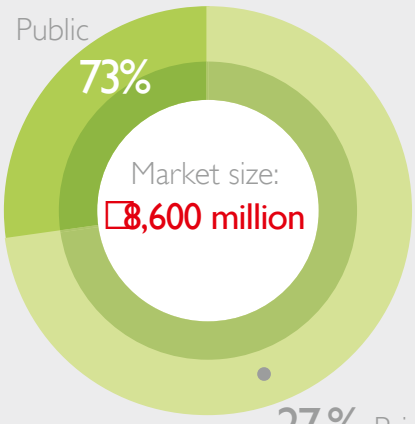
Export	Import
75%	80%
€ 35,100 million	€ 36,900 million
Share in total production «	» Share in domestic market

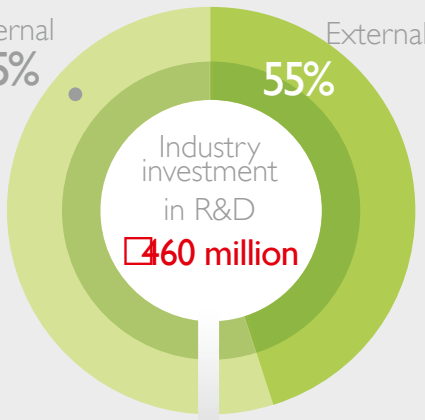
- Trade balance - **€ 1,800 million**

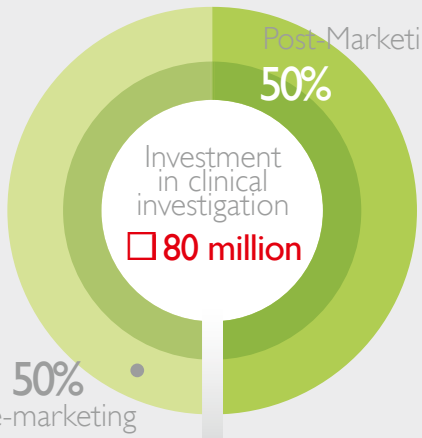
9th medical device importer

12th medical device exporter

Italian market for medical devices in figures (2010)







Share of R&D on total production **6.8%** Total R&D investment **€ 640 million**

The province of Bologna is also home to several biomedical companies involved in production of orthopaedic devices (implantable prostheses, artificial limbs, ortheses).

There is a relatively high production of electro medical and diagnostic devices in Milan and biomedical instruments and in vitro devices in Florence; in Rome and Padua the profile is much more heterogeneous.

84% of direct manufacturers uses third party production, accounting for **25% of the product's final cost** with relevant differences among the various markets: the highest variations are registered for equipment (electro medical, diagnostic and biomedical), while the lowest are related to single-use disposable products (biomedical) and consumables (reagents and in vitro diagnostics).

Most of the productive process takes place in Italy, due to a very limited attitude of the medical sector to delocalize it in countries with lower labour costs.

R&D investment **represents 6.8%** of national production, while investment in clinical investigation accounts for **over 2%** of the turnover of manufacturers and multinationals, **48%** coming from pre-marketing studies and **52% from post-marketing studies.**

Imaging diagnostics – The market for **electromedical equipment** was estimated at □.3 billion in 2009, of which imaging diagnostics accounted for □357 million.

Imaging diagnostic devices in public health centers and private contractors, 2009

Device	Number	Density (1 mn inhabitants)
Ecotomograph	16,082	267.8
Computed gamma camera	711	11.8
Magnetic Resonance Tomograph	1,245	20.7
Computed Axial Tomograph	1,826	30.4
Positron Emission Tomograph	36	0.6
Integrated CT/PET system	82	1.4
Digital angiography system	677	11.3
Integrated CT gamma camera system	63	1.0
Panoramic dental x-ray	815	13.6
Ortopantomograph	1,749	29.1
Mammograph	1,842	189.2

Source: Ministry of Health

Although the life cycle of high-tech imaging devices is quite short, the market is influenced by the **delays in payments from the public health system.** Since the large majority of enterprises in the sector is of limited size, these constraints weigh on their ability to invest and innovate.

Average age of imaging equipment

	0-5 years	5-10 years	>10 years
CAT scan	70%	26%	4%
NMR	83%	17%	0%
Conventional x-ray	19%	19%	48%

Source: Ministry of Health

As the public sector is the main buyer of medical equipment, the level of public health expenditure plays a relevant role in shaping the market for these devices. In order to take into account the across-country variations of public expenditure, it is necessary to note that the **Italian regions with the highest public annual expenditure on health (over or around □8 billion) are Piedmont, Lombardy, Veneto, Emilia-Romagna, Lazio, Campania and Sicily.**

However, on a per capita basis **public health expenditure** is quite even, ranging between **□,500 and □2,000** across the whole country, meaning that relevant regional differences are mainly due to population density. In Lombardia, Lazio, Puglia and Sicily there is, moreover, the highest percentage (>40%) of private contractors providing services to the public health systems.

A study conducted by **ASSOBIOMEDICA** comparing the data for three types of imaging diagnostic devices (Ecograph, Computed Axial Tomograph and Nuclear Resonance Imaging equipment) shows that the number and density of such devices in **public healthcare centers is higher in northern Italy,** whereas in the **private sector the trend is inverse as southern regions** have the highest density. There is therefore a comparative lack of adequate coverage for these types of devices in public sector facilities across southern Italy.

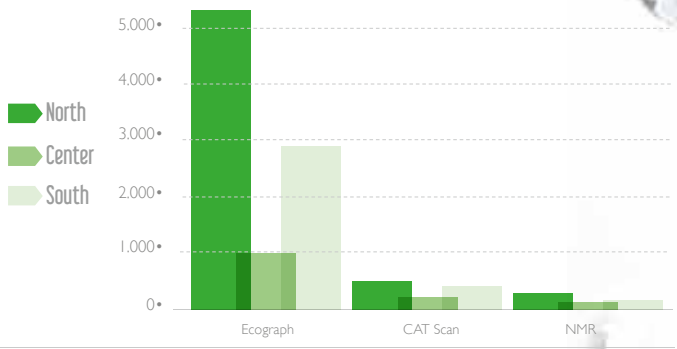
As regards foreign markets, although the minor presence in Europe and USA, **Italian products are gaining consistent position in emerging markets** where the growth of demand for quality health services and devices attracts Italian exports.

Number of selected imaging diagnostic devices in Italy

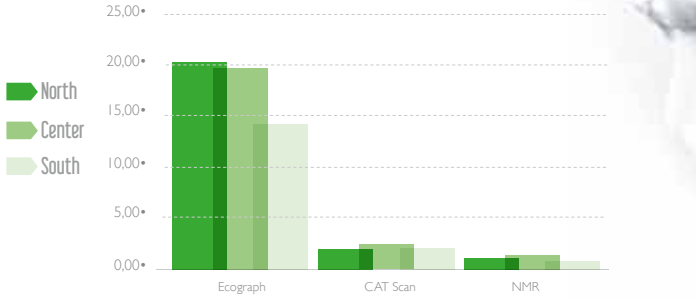
Ecographs: 10,000
Computed Axial Tomograph: 1,200
Nuclear Magnetic Resonance: 600

Source: ASSOBIOMEDICA

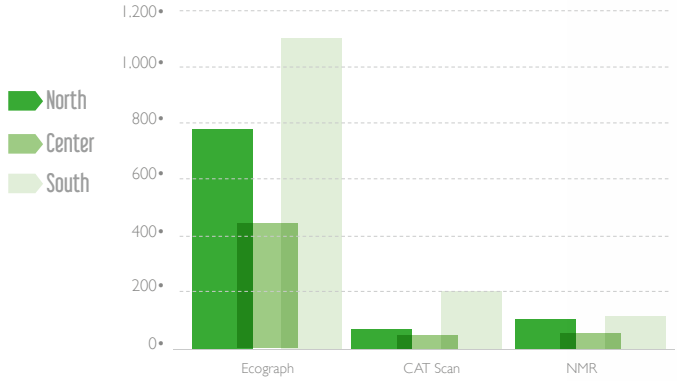
Number of selected imaging diagnostic devices - public sector



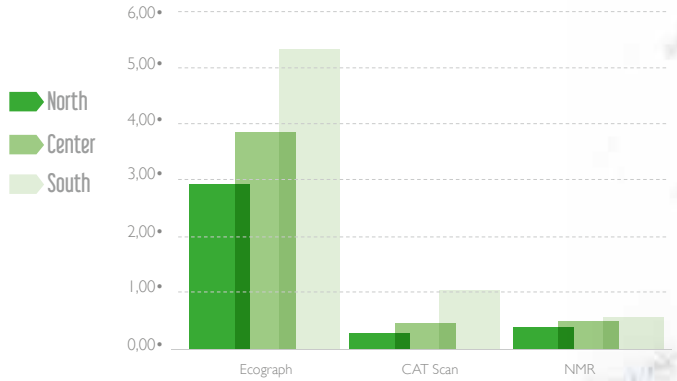
Number of selected imaging diagnostic devices per 100,000 inhabitants - public sector



Number of imaging diagnostic devices - private sector



Number of imaging diagnostic devices per 100,000 inhabitants - private sector



Source: ASSOBIOMEDICA

Italian Medical Industry:
Special Insight on Imaging Diagnostics

In the following pages INFOMEDIX presents "The excellence of Italian radiology": articles and interviews featuring Italian companies leaders in the field of x-ray and imaging diagnostics.

Italian devices enjoys a reputation of reliability and fine design, due to a long established manufacturing tradition that accounts for the success of its export-oriented production.

NewTom – QR s.r.l.

Contact person: Claudiano Tagliareni
Email: info@qrverona.it
Tel: +39 045 8202727
Website: www.newtom.it

What role does your company play in the field of radiology?

QR s.r.l. is the name that stands behind NewTom units. We were the first to use Cone Beam in dental field, introducing QR DVT-9000 in 1996. NewTom's 20 plus years of experience and success in research, development, manufacturing and distribution of NewTom products affirms our commitment to excellence and quality.

What is your core product?

According to our clients' needs, we offer different products: **NewTom's VGi for maxillofacial radiology and mobile solutions, NewTom GiANO for dental practices (available from January 2013), and NewTom 5G for medical radiology.** They employ CBCT technology, with a low dose, in order to obtain high level quality images, and are compatible with third party software available on the market.

Do you have an innovative product or service? Could you describe your innovation challenge?

All our products are designed by NewTom's R&D department, using the most advanced components available on the market (rotating anode, smallest focal spot, flat panel, smallest voxel size). We create our own firmware and software for analysis (NNT) applying specific reconstruction algorithms to provide a full range of information.

What is the future focus in terms of research and development for your company?

NewTom intends to focus on improving the use of CBCT technology not only in the dental field, but also for medical and veterinary applications. We plan to further develop our software, enhancing its performances and increasing its compatibility with all available software and devices.

What are your short and long-terms market plans?

The company plans to participate in 2013's most important events for dental, medical and veterinary radiology to demonstrate our reputation of Italian excellence to the worldwide public. We also intend to promote the creation of mobile radiology centers, which are already widely used in the US.

What was the impact of the economic crisis on the radiology field?

We can't precisely estimate the effects of the economic crisis, since our portfolio includes products for different applications that are sold globally. One downside of the crisis is the difficulty that clients are facing in obtaining financing. Thanks to new innovative features included in our products, sales in medical and veterinary fields are increasing, broadening our global markets and balancing the risk.

Which countries were most affected by the recent macroeconomic conditions and what are the reasons?

The local economy brought countries as Greece, Spain and some parts of East Europe, to experience a deeper crisis than other powerful and technologically advanced countries, which were prepared to face up this situation.

What role does Italy play as a producer of excellence in the radiology field?

Italy has a leading role in the radiology field and the proof is the presence of several Italian companies at the main radiological events all over the world. Even if the Italian market suffered from the economic crisis, it is still considered a reference point for radiology.

In which branches of the radiological industry does Italy play a leadership role?

Italy still plays an important role in the fields listed below, thanks to a multitude of brands that represent high technology, design and reliability.

- MRI
- Informatic Radiology
- Mammography
- DR
- CT/CBCT
- Dental Radiology

Do BRIC nations (Brazil, Russia, India, China) represent the future core market for radiology?

Of course, Brazil and China have been given us gratification from the high number of sales and the wide products knowledge. Russia and India offer large market segments but it is crucial to find good and reliable partners.

What are future radiology market trends?

I believe that in 2013 the markets with the major trends for our group will be dental radiology, especially in the segment of machines with both 2D and medium FOV CBCT devices, and medical radiology with recent CT/MRI and X-ray devices for operating theatre.

IAE

Contact Person: Elio Bettoni
Job Title: General Manager
E-mail: bettoni@iae.it
Telefono: 0039 02 66 3032 55
Website: www.iae.it

What role does your company play in the field of radiology?

IAE, an X-Ray tube manufacturer leading company , plays the role of provider of an important and essential component for all manufacturers of X-ray equipment. Thanks to that, the company is very well placed in the high concentration of manufacturers of radiological equipment that exist in Italy, especially in the North and Central areas, and is strongly present as well in other geographical domains.

What is your core product?

Our core is very diversified , including the whole range of rotating anode X-ray tubes, from small tubes for portable devices for hospital wards, to mid-range of general diagnostics and mammography, up to tubes for average size CT scanners.

Do you have an innovative product or service? Could you describe your innovation challenge?

Due to its nature of a component , even if important, the product must be developed within the boundaries of the target equipment. **Thus innovation is mainly expressed in capturing and possibly anticipating the needs of new applications and solutions for our customers.** This can be done with flexibility and fast response that is peculiar to the medium size of the company. In the last years we dedicated our efforts to the development of some innovative systems of heat dissipation, which enabled our customers to face higher-level applications or respond to requests for more intensive patients throughput in diagnostic departments.

What is the future focus in terms of research and development for your company?

At present there is a considerable interest among our customers in mammography equipment, where digital technologies allow to face innovative methods of imaging. **We respond to that with design upgrading and new developments, also with non-conventional construction technologies.** This is flanked by a constant action of review and improvement of our production processes, with the multiple purposes of consolidating the quality, keeping a competitive edge and reducing the environmental impact.

What are your short and long-terms marketing plans?

A worldwide participation to International Congresses and exhibitions of Radiology is the main vehicle of knowledge and penetration of our products into new markets.
The presence of our agents in strategic areas allows us to satisfy quickly special requests of our customers. We pay a special attention to responding directly and timely to questions of different nature that come from various interlocutors.

What was the impact of the economic crisis on the radiology field?

Of course we have observed a significant reduction of business activities in the European markets of the sector. However, we coped to this by gaining shares of equal or greater extent in emerging or far away markets , especially the Far East, Eastern Europe and South America.

What role does Italy play as a producer of excellence in the radiology field?

As mentioned at the beginning, Italian industries have a predominant role in the field of radiology and it is not out of place to say that Italy is the country with the highest percentage of producers of X-ray equipment, both as independent role players and as OEM suppliers to large multinational companies .

In which branches of the radiological industry does Italy play a leadership role?

As far as we can estimate from our personal point of view, we see considerable activity in the field of innovation in DR equipment, and an important presence in mammography systems .

Do BRIC nations (Brazil/Russia/India/China) represent the future core market for radiology?

Certainly, these are the areas in which we observed a rapid economic development, with a clear trend of continued growth.

What are future radiology market trends?

Digital technologies, with their related components, are a big boost to the renewal of diagnostic installations, as well as to operating methods, both local and remote, of their use.

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GMM,
know-how & innovation in diagnostic imaging

General Medical Merate, GMM, has been dealing in the medical radiology field for over 50 years: since it was founded, in 1952, GMM has been developing and manufacturing state-of-the-art equipment for the different application needs in diagnostic imaging.

The results of these past few years, despite the deep economic crisis that has hit all sectors, **reconfirm GMM's leadership among national manufacturers in terms of both turnover and investment in research and innovation.**

- *OPERA Swing,*

Multifunctional R/F remote-controlled system with digital flat panel detector

And, definitely, thanks to its innovation capacity and design skills, GMM fully exploits the technological potential and produce systems that ensure not only unmatchable user-friendliness and application versatility, but also total safety for both operators and patients.

On the other hand, **the "quality" principle,** that has been inspiring GMM since it was founded, guarantees the full compliance of both GMM organizational system and products with the requirements set by national and international Standards applying to medical devices: our internal procedures related to development, validation and production, follow the good manufacturing practices, meet the most stringent testing processes, satisfy the most accurate inspection criteria.

Our range of products includes **equipment for conventional and digital radiology:** analog and digital remote-controlled systems and systems with flat panel detector; radiographic systems for conventional and digital radiology, DR systems; specialized equipment, such as C-arms, mobile units, mammography systems.

Since always, our "core product" is represented by the remote-controlled R/F table of the OPERA T series that is available in six different configurations (with Image Intensifier and TV chain system, with digital imaging system, with cutting-edge flat panel detector) and boasts installation sites and important referential centres all over the world thanks to its well-known characteristics of safety, reliability and operational efficiency.

The **revolutionary OPERA Swing system** stands out among the main products of GMM range as well: OPERA Swing is a multifunctional R/F remote-controlled system specifically conceived to ensure the best combination with digital flat panel detector, thus allowing the operator to manage, through a unique highly integrated solution, the most enhanced examinations in both digital radiography and fluorography in any diagnostic procedure: skeletal system, thorax, lungs, gastroenterology, gynaecology, paediatrics, emergency, digital angiography, tomography, reconstruction of both the column and lower limbs (stitching) … the actual "all-in-one" system.

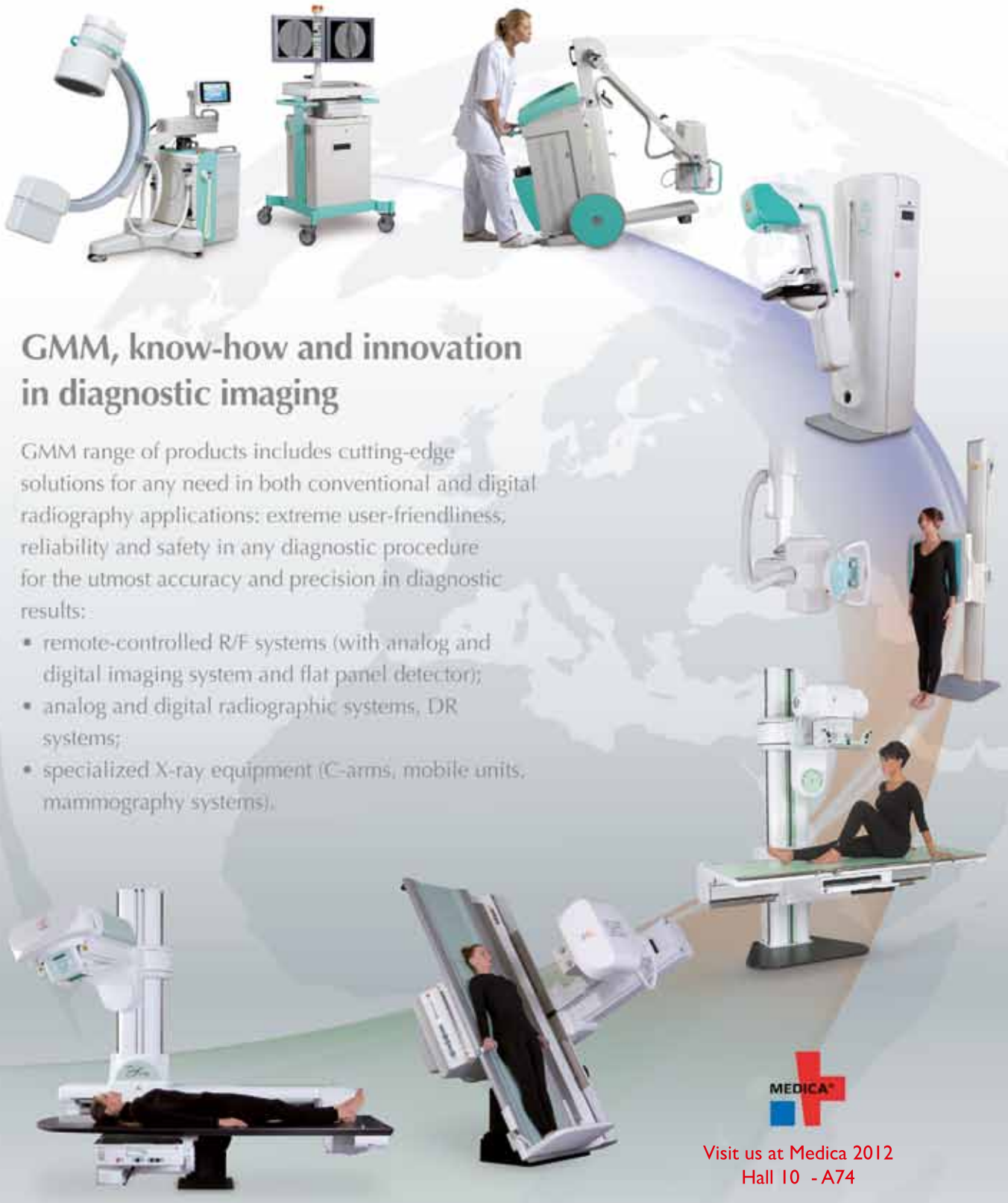
The ability to "evolve" hand in hand with technology allows GMM to constantly renew and innovate the range of products with a view to offer equipment that actually reflect and satisfy the operators' needs.

And, also for the future, our mission and vision provide for continuing to evolve, improve the performances of our systems, optimising their quality-price ratio as well; an objective, this last one, that underpins our marketing strategy, which also aims at maintaining our market leadership position and strengthen our presence in emerging markets, also through the establishment of "local entities" (e.g., GMM India).

General Medical Merate S.p.A.
info@gmmspa.com - www.gmmspa

- *OPERA T,*

A complete series of remote-controlled R/F tables



GMM, know-how and innovation in diagnostic imaging

GMM range of products includes cutting-edge solutions for any need in both conventional and digital radiography applications: extreme user-friendliness, reliability and safety in any diagnostic procedure for the utmost accuracy and precision in diagnostic results:

- remote-controlled R/F systems (with analog and digital imaging system and flat panel detector);
- analog and digital radiographic systems, DR systems;
- specialized X-ray equipment (C-arms, mobile units, mammography systems).

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I.M.D. proposes itself as an ideal partner for the production of radiological assemblies of medical units or industrial control systems, putting at disposal of its partners its expertise in the industrialization of systems, their interfacing and certification. The aim of this specific offer of cooperation is to optimize the implementation of each component into the system, and to improve the power performance according to the partner's needs for a specific typology of application.

The adaptability to specific applicative needs allows the optimization of the whole project, with a radical and important cost reduction. The company mission is the research and development of solutions for the best exploitation of the technology of High Frequency Monobloc X-ray Generators, for the application on board of both medical and industrial control systems.

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Visit us at MEDICA 2012- Hall 10- Stand C50

Villa Sistemi Medicali

Contact Person: Matteo Lavezzini
E-mail: marketing@villasm.com
Telefono: +39 02 488591
Website: www.villasm.com

What role does your company play in the field of radiology?

Since 1958, Villa Sistemi Medicali is committed to the development of X-ray products and **is currently one of the few companies worldwide to design, manufacture and market radiological systems for both dental and medical applications.** Leveraging more than 50 years of experience in the X-ray field, the company's know-how covers all technologies which can create effective solutions for any radiographic environment.

What is your core product?

The core of our production is represented by the **Apollo,** remote controlled systems for Radio-Fluoroscopy applications, available either analogic or full-digital DRF, as well as by the **Rotograph dental panoramic units,** recently evolved also to **3D imaging featuring "Cone Beam" technology.**

What is the future focus in terms of research and development for your company?

VSM constantly invests over 4% of total annual revenues in Research & Development, to incorporate in its systems the latest available technologies. **We are launching right in this period a new unit for dental radiology,** offering to users innovative solutions particularly in terms of user interface. Shortly we will finalize also new products completing our Medical product catalogue, focusing particularly on Digital Radiology.

What was the impact of the economic crisis on the radiology field? Which countries were most affected by the recent macroeconomic conditions and what are the reasons?

The market of electromedical devices, in general, is definitely slowing down particularly in the Euro-zone countries, plausibly due to the efforts of the governments to contain costs of the Public health service. However, in other regions of the world, there's a growing need for high-quality medical instruments, including X-ray devices, thanks to the increasing number of people accessing services willing to improve their health condition.

What role does Italy play as a producer of excellence in the radiology field?

In the market of X-ray products, made in Italy solutions are generally judged excellent thanks to the very good tradition of local manufacturers, present on the market since many years. Italy keeps the skills and the "know how" to produce original solutions, also in terms of design and ergonomics.

What are future radiology market trends?

The constant switchover to **Digital Radiology** will go on improving the quality of the offered services, principally in terms of dose reduction and treatment of images. These newer and newer "digital chains" will be integrated in systems more and more devoted to speed up the use of the machines, with consequent improvement of patient throughput.

Some innovations in BMI's world

BMI Biomedical International Srl can trace its history back to 1994, when we started distributing worldwide a complete range of radiological medical equipments, providing solutions to the demanding needs of modern radiology. Besides the recently introduced DR products JOLLY PLUS DR and BUS-DR we are now proud to display our brand new BCA-PLUS Mobile C-Arm series, featuring:

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The Amorphous Selenium is the most advanced technology to produce the highest signal/noise ratio since direct conversion grants image sharpness and very high quality. Helianthus BYM is fitted with fully motorized isocentric C-Arm (vertical and rotation movement) that allows all breast projections without moving the patient and without adjusting the height of the C-Arm and is upgreadable for stereotactic biopsy.

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Highlights

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- Radiographic systems, for routine and specialized radiography;
- R/F systems, for all radiographic and fluoroscopic examinations with advanced Digital Imaging Systems;
- Mammographic Units
- Endoral and Panoramic dental units

BMI Biomedical can also provide components such as monoblocs, generators, Toshiba X-ray / Image Intensifier tubes for the manufacturing industry

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European regulatory framework updates

On 30 August 2012 new consolidated lists of references of harmonised standards under the three (main) medical devices directives were published in the Official Journal of the European Union.

The harmonised **European standards**, the references of which have been published in the Official Journal C 262, provide solutions for compliance and confer a presumption of conformity with the essential health and safety requirements of the medical devices directives that they cover.

However, the use of **harmonised standards** remains voluntary and manufacturers can choose whether or not to follow a harmonised standard to manufacture their products. Manufacturers may thus use other technical solutions providing for an equivalent level of safety. In that case, they must be able to prove that their products are in conformity with the mandatory essential health and **safety** requirements, taking due account of the state of the art. The following summary of new and changed standards is an extract from the ***European Commission website*** and does not have any official validity; for legally valid reference please check the ***Official Journal*** on **http://eur-lex.europa.eu**

Directive 90/385/EEC for active implantable medical devices

Standard	Subject
EN ISO 11137-2:2012	Sterilization of health care products - Radiation – Part 2: Establishing the sterilization dose (ISO 11137-2:2012)
EN ISO 13485:2012; EN ISO 13485:2012/AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)

Directive 93/42/EEC for medical devices

Standard	Subject
EN 1865-3:2012	Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher
EN 1865-4:2012	Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair
EN 1865-5:2012	Patient handling equipment used in road ambulances - Part 5: Stretcher support
EN ISO 5359:2008/A1:2011	Low-pressure hose assemblies for use with medical gases
EN ISO 11137-2:2012	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2012)
EN ISO 13485:2012; EN ISO 13485:2012/AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 13727:2012	Chemical disinfectants and antiseptics - Quantitative suspension test for the evalua tion of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)
EN ISO 14971:2012	Medical devices - Application of risk manage ment to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 25539-1:2009/AC:2011; EN ISO 25539-2:2009/AC:2011	Cardiovascular implants
EN ISO 81060-1:2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)
EN 61217:2012	Radiotherapy equipment - Coordinates, mo vements and scales IEC 61217:2011
EN 60601-2-33:2002/A2:2008/AC:2008; EN 60601-2-52:2010/AC:2011	Medical electrical equipment

Directive 98/79/EC for in vitro diagnostic medical devices

Standard	Subject
EN ISO 13485:2012; EN ISO 13485:2012/AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN ISO 14971:2012	Medical devices - Application of risk manage ment to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

Fostering EU's attractiveness in clinical research: Commission proposes to revamp rules on trials with medicines

Boosting clinical research in Europe by simplifying the rules for conducting clinical trials is what today's proposal from the Commission is about. **Clinical trials** are tests of medicines in humans and give patients access to most innovative treatments.

At the same time, **clinical research** with over 20 billion Euros of investment per year in the EU makes a significant contribution to the growth policy of the Europe 2020 agenda.

Clinical trials are vital to develop medicines and to improve and compare the use of already authorised medicines. The data generated in clinical trials are used by researchers in publications, and by **pharmaceutical companies** applying for marketing authorisations.

Once implemented, the measures proposed today will speed up and simplify the authorisation and reporting **procedures,** while maintaining the highest standards of patient safety and robustness and reliability of data.

The measures will also better differentiate the obligations according to the risk-profile of the trial, and improve transparency including on trials done in third countries.

John Dalli, European Commissioner for Health and Consumer Policy, said: ***"Patients in Europe should have access to the most innovative clinical research. Clinical trials are crucial for developing new medicines and improving existing treatments. This is why today's proposal significantly facilitates the management of clinical trials, while maintaining the highest standards of patient safety and the robustness and reliability of trial data. 800 million Euros per year could be saved in regulatory costs and boost research and development in the EU, thus contributing to economic growth."***

The proposed Regulation, once adopted, will replace the **'Clinical Trials Directive' of 2001**. It has ensured high level of patient safety, but its divergent transposition and application led to an unfavourable regulatory framework for clinical research, thus contributing to a **decrease of 25% of clinical trials** conducted in the period between 2007 and 2011: in 2007, more than 5,000 clinical trials were applied for in the EU while by 2011 the number had dropped to 3,800.

The new legislation proposed by the Commission will take the form of a Regulation. This will ensure that the rules for conducting clinical trials are identical throughout the EU. In particular, it will make it easier to conduct multinational clinical trials in Europe. Some concrete proposals are:

- An **authorisation procedure for clinical trials** which will allow for a fast and thorough assessment of the application by all Member States concerned and which will ensure one single assessment outcome.

- **Simplified reporting procedures** which will spare researchers from submitting largely identical information on the clinical trial separately to various bodies and Member States.

- **More transparency** on whether recruitment for participating in a clinical trial is still ongoing, and on the results of the clinical trial.

- The possibility for the **Commission to conduct controls in Member States and other countries** to make sure the rules are being properly supervised and enforced.

The legislative proposal will now be discussed in the European Parliament and in the Council. It is **expected to come into effect in 2016.**

For more information on clinical trials:
http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm
MEMO/12/566

The European Union (EU) has reformed the rules for importing into the EU active substances for medicinal products for human use.

As of 2 January 2013, all imported active substances must have been manufactured in compliance with standards of good manufacturing practices (GMP) at least equivalent to the GMP of the EU. The manufacturing standards in the EU for active substances are those of the 'International Conference for Harmonisation' – ICH Q7. As of 2 July 2013, this compliance must be confirmed in writing by the competent authority of the exporting country. This document must also confirm that the plant where the active substance was manufactured is subject to control and enforcement of good manufacturing practices at least equivalent to that in the EU.

Some important points are highlighted in the leaflet published by the European Commission on the subject:

- Written confirmation is issued by the regulatory authority of the country where the manufacturing site is located and shall be requested from that authority.

- Written confirmation is issued per manufacturing plant and for each active substance(s) manufactured on that site.

- Each imported consignment has to be accompanied by the written confirmation issued by the regulatory authority or its copy.

- The Commission publishes a list of countries that are considered as having equivalent rules for good manufacturing practices to those in the EU. Active substances manufactured in such countries do not require a written confirmation.

- Even if a manufacturing site has recently been inspected by an EU Member State or by the European Directorate for the Quality of Medicines (EDQM) of the Council of Europe, it still does require written confirmation. However, exceptionally and where necessary to ensure the availability of medicinal products, following inspections by an EU Member State, a Member State may decide to waive the need for a written confirmation for a period not exceeding the validity of the GMP certificate.

- Written confirmation is also required where there is a 'mutual recognition agreement' between manufacturer's country and the EU.

More information is available here:
http://ec.europa.eu/health/human-use/quality/index_en.htm
The leaflet with the letterhead of the issuing regulatory authority is available here:
http://ec.europa.eu/health/files/documents/active_pharmaceutical_ingredients_leaflet_en.pdf

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Henry Schein – a global company that cares

Henry Schein, Inc. (NASDAQ: HSIC) is the world's largest provider of health care products and services to office-based dental, medical and animal health practitioners. The Company also serves dental laboratories, government and institutional health care clinics, and other alternate care sites. Henry Schein employs nearly 15,000 Team Schein Members and serves approximately 775,000 customers. Headquartered in Melville, N.Y., the Company has operations or affiliates in 26 countries.

Henry Schein offers a comprehensive selection of products and services, including value-added solutions for operating efficient practices and delivering high-quality care. The Company also offers its customers exclusive, innovative technology solutions, including practice management software and e-commerce solutions, as well as a broad range of financial services.

In Europe, Henry Schein has a highly-experienced team of more than 4,000 Team Schein Members serving the medical, dental, animal health and technology markets. As a leader in the European medical market, the company serves approximately 75,000 medical customers through its subsidiaries in Austria (Henry Schein Medical), Germany (Henry Schein Medical), The Netherlands (Henry Schein Medical), Spain (Henry Schein España), Switzerland (Heiland Schweiz) and the United Kingdom (Henry Schein Medical – the new face of Porter Nash). Henry Schein's European medical business offers an extensive selection of medical supplies, equipment, trainings, specialized products and practice solutions to support the Company's customers in operating their practices efficiently, attaining their business goals, and delivering the highest quality care to their patients.

Henry Schein globally combines its traditionally customer-oriented engagement with the participation in world-class service logistics and know-how – always remaining a locally specified health care products and service provider dedicated to the individual needs of the customer.

For 2012, the Company has once again been named to Fortune's list of the "World's Most Admired Companies". Henry Schein earned the highest ranking in its industry, "Wholesalers: Health Care". Furthermore, the Company has been named to Ethisphere's 2012 list of World's Most Ethical Companies for the first time. Out of more than 5,000 nominations for the World's Most Ethical Companies award this year, Henry Schein was named to the list of 145 companies for raising the bar for ethical standards within the health care industry through exemplary ethical leadership, worldwide business standards and commitment to corporate social responsibility.

Henry Schein Cares, Henry Schein's global corporate social responsibility program, enhances access to health care for underserved and at-risk communities around the world. Firmly rooted in a deep commitment to social responsibility and the concept of enlightened self-interest championed by Benjamin Franklin, the philosophy behind Henry Schein Cares is a vision of "doing well by doing good".

For more information visit the Henry Schein Web site at www.henryschein.com.

Team Schein Members in front of the headquarters in Melville, New York

Team Schein Member preparing a Henry Schein Cares product donation

What it takes to become a price champion

Findings from the Global Pricing Study

By Klaus Hilleke, Georg Tacke and Robert Dumitrescu

"When it comes to the prices we pay, we study them, we map them, we work on them. But with the prices we charge, we are too sloppy!" **complained the CEO of General Electric, Jeffrey Immelt, in 2006.**

Simon-Kucher & Partners put an end to the insecurity and shed light on pricing know-how and profit culture across countries and industries. We asked over 3,900 high-level decision makers from all major service and manufacturing industries around the world **how they set their prices.** Almost half of the respondents from Europe, the US and Asia are from companies with more than one billion euros in sales; C-level executives account for one-third of the respondents. From the U.S. alone we had 643 respondents. The main findings in a nutshell: **Not everyone gets what they deserve. And weak pricing cuts profits by 25 percent.** As pricing specialists we know that pricing is the most important profit driver. But how much do managers actually know? Do they get the money for the value they deliver? What are the differences between the United States, Asia, and Europe? How do industries such as logistics and telecommunications differ from pharmaceuticals, biotech/medtech companies? In cooperation with PPS and the IE Business School in Spain we conducted the largest pricing study ever with remarkable results. One thing has not changed since 2006: Some companies are still sloppy. But there are also those who have done their homework and become excellent pricers. Some countries and several industries outperform others and offer best practice examples. The key question is: **How do you become a price champion?**

In this article, we will present the findings of the Global Pricing Study 2011 and then outline the most important lessons for managers. The three main areas at a glance are:

1. Pricing power is still untapped

- 65 percent of the companies are not able to charge the prices they deserve.
- Only 35 percent of the companies have sufficient pricing power to achieve the "right" price for their products/services.
- Low pricing power is costly. It cuts profits by 25 percent.
- Brand and product value are the primary drivers of high pricing power.

2. Price wars continue

- 46 percent of companies think they're in a price war.
- The extent of price wars differs greatly by country and industry; the Japanese market has by far the highest level (84 percent), followed by Italy (69 percent) and Spain (65 percent).
- 83 percent of companies in a price war blame competitors for starting it.

3. The inflation threat is underestimated

- Companies get only half of what they expect when they try to raise prices
- Only about one-third of the companies is able to achieve at least 75 percent of the originally planned price increase.
- Telecommunications (25 percent) and life sciences (29 percent) have the weakest performance when it comes to implementing price increases.
- 68 percent of the companies plan to increase prices below or in line with inflation; given the poor price implementation performance, this will not be enough.

Pricing power untapped

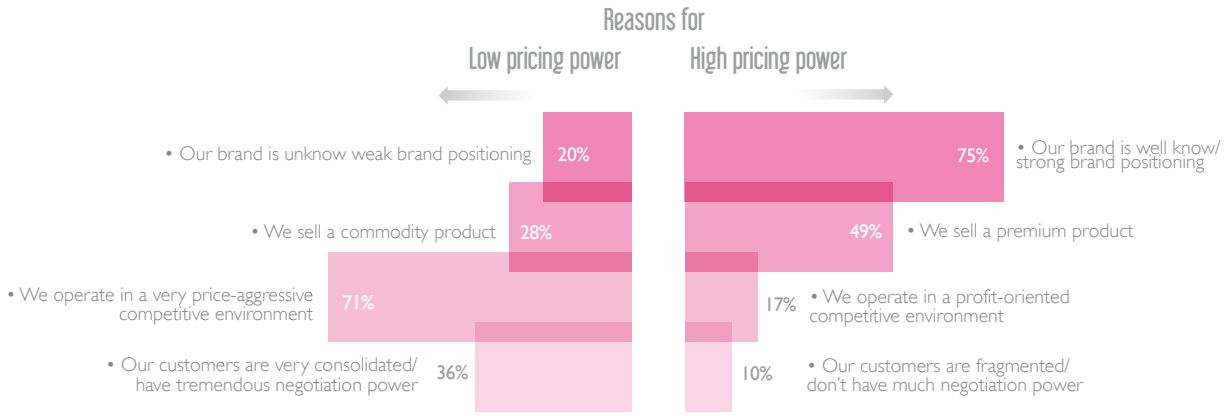
Pricing power is the ability of a company to get the market prices it deserves for the value it delivers to its customers. Those companies can charge a premium even in a commoditized or competitive market. In other words, pricing power is a key capability and essential to protect profits. In turbulent times like these and given the generally poor price performance, many companies can't afford to lose even a few percentage points of profit. Only one-third of the study respondents has sufficient pricing power and knows how to turn value into money. The remaining 65 percent of companies admit to having only very little or no pricing power, which is why it's clear from the beginning that the target price cannot be achieved. This weak performance is costly because it cuts profits by one-quarter.

Industries and countries vary considerably in this regard. Chemicals (14 percent) and transport & logistics (19 percent) have the lowest pricing power. Pharmaceuticals, biotech/medtech (53 percent), construction (49 percent) and consumer goods (47 percent) are ranked best. That pharmaceutical companies outperform the others doesn't come as a surprise. It's in the genes of pharma players to exploit the potential of products to the maximum extent. Already at the R&D stage are they beginning to think about the pricing and market access strategy for their new product – often seven to ten years before the drug reaches the market. This contrasts strongly from the transport and logistics industries where, for example, companies are trying to fully utilize their logistics network, only to find themselves in fierce competition and price wars. In the end they often give away their services close to marginal costs. Pharmaceutical companies have patent protection, they avoid price wars and aim to maximize profits rather than market share – these are simple things. **But being in a particular sector does not mean you are fixed to a level of profitability.** In all industries there are large groups of companies with high pricing power. It is up to other companies to become price champions and gain entry to these groups. How do the countries perform? Battered markets such as Italy and Spain are the weakest countries when it comes to pricing power. Companies in Poland (44 percent), the US (43 percent) and France (40 percent) are ranked best. They more often achieve market prices that are in line with the value they offer.

What distinguishes the power pricers from the low performers? The primary drivers for high pricing power are customer value and brand. Every company has the ability to achieve high pricing power. **If a company can offer its customers real value and communicate that through a top brand, this will translate into money.** Unfortunately, in many cases managers deceive themselves and excuse the weak performance of their company by blaming others: 71 percent of the study respondents point the finger at tough competition as the source of their monetization woes. 36 percent of the managers place the blame on customers and state that their customers are very consolidated and have tremendous negotiation power. But oftentimes the company's own product assortment is guilty: *"We sell a commodity product."*

46% of managers consider their company to be in a price war, and 83% of those blame competitors for starting it

Companies with low pricing power primarily blame others (aggressive competitors, customers), even though value and brand lies in their own hands.

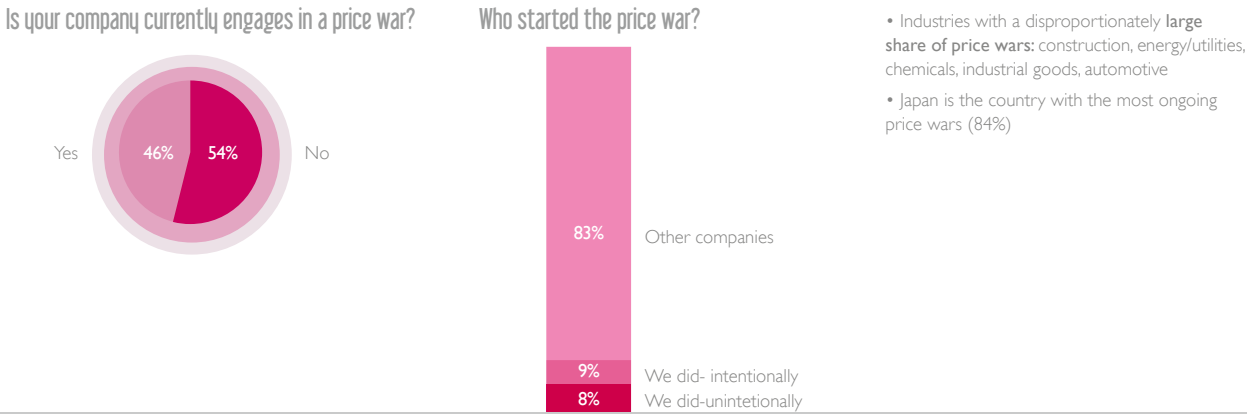


Source: Simon-Kucher & Partners Global Pricing Studies 2011

These are all excuses that avoid getting to the bottom of the problem. **Poor pricing performance is not a question of fate;** it is largely up to each company to decide whether it follows the road toward becoming a pricing champion and achieving higher profits than its peers or the road toward price wars with ruined price levels. **Our detailed analysis of almost 4,000 companies reveals that there are no structural reasons for the major monetization weaknesses.** We identified three fundamental causes that make the difference: Insufficient monitoring, a lack of pricing know-how and poor strategies. The results prove that power pricers do their basic pricing homework and have a different mindset. **They simply avoid the biggest mistake: focusing strictly on market shares and volume.** The key piece of advice we therefore give to our clients is to start with strategic goals and assess the right price strategy. You have to ensure you are clearly focused on profit instead of volume or market share. By redirecting the whole organization towards pricing power and making it one of the top KPIs, successful companies achieve higher profits and perform better in many aspects. The fate of those who mainly focus on volume and market share is illustrated by the study results, too. They get tied up in price wars.

46% of managers consider their company to be in a price war, and 83% of those blame competitors for starting it

Companies with low pricing power primarily blame others (aggressive competitors, customers), even though value and brand lies in their own hands.



Source: Simon-Kucher & Partners Global Pricing Studies 2011

Market share obsession leads to price wars

46 percent of companies state that they are engaged in price wars. The vast majority of managers from those companies (83 percent) blame their competitors for triggering them - although statistically this is almost impossible.

Leading the country comparison with 84 percent, Japan is by far the most militant market, followed by Italy (69 percent) and Spain (65 percent). Japan is not a big surprise. Almost by tradition, Japanese managers mainly focus on volume and market share. The result is fatal: Industrial enterprises in Japan have by far the lowest returns. Industries with a disproportionately large share of price wars are construction, energy & utilities, chemicals, industrial goods and automotive. **Managers from the pharmaceutical, biotech and medical technology industries are smarter and engage less in price wars (only 36 percent).**

In general, we observe that price wars are sparked by an unhealthy obsession with market share and volumes. The majority of respondents in our study describe their industry as volume oriented. One respondent pointed out: "If you ask your people to strive for volume, you should not be too surprised when you end up in a price war." The effect of price wars on profits is disastrous for all sides. There are no winners—except the customer. **That's why our key piece of advice to clients is to avoid price wars if at all possible.** Managers should strive for profit, not for market share.

The underestimated inflation threat

So far, pricing has been neglected by many companies. With inflation around the corner, they will pay the price: The survey findings reveal that the vast majority of companies are able to achieve only half of their targeted price increases. That means you only get 53 percent in the end, although you wanted 100 percent. This is why managers urgently need to set higher targets right from the beginning. **Only 36 percent achieve at least three-quarters of their originally planned price increase.**

Lacking experience, managers use the inflation rate as a benchmark for price increase targets. 68 percent of managers plan to increase prices below or in line with inflation rates. Using the inflation rate as a benchmark is fatal for those who are weak in price implementation. This won't be enough. They'll probably end up paying the difference. To cope with the inflation risk, pricing know-how distinguishes the smart companies from the low performers. They improve their price implementation performance and set high targets for price increases which take that performance into account.

How to plan and increase prices systematically

Although price increases are essential for survival in inflation periods, we have observed that most managers are insecure about how to plan and implement price increases. There are a few steps though that can help managers. First and foremost, you need a consistent and systematic process for pricing. For every single activity companies have detailed processes with descriptions and explanations, but when it comes to price increases many don't exactly know what to do. We have developed such a process. **Start with the price increase targets, select the right instruments, prepare the price increase and, finally, execute it.** The entire process must be supported by systems tools and data; as always, you have to monitor the result. That may sound like a no-brainer. But many companies have no clue about the real net effect of a price increase. Why? Because price increases are often accompanied by "goodies", discounts, give-aways, customer-friendly payment terms, etc. Many fail to factor in the effect of these customer-friendly measures.

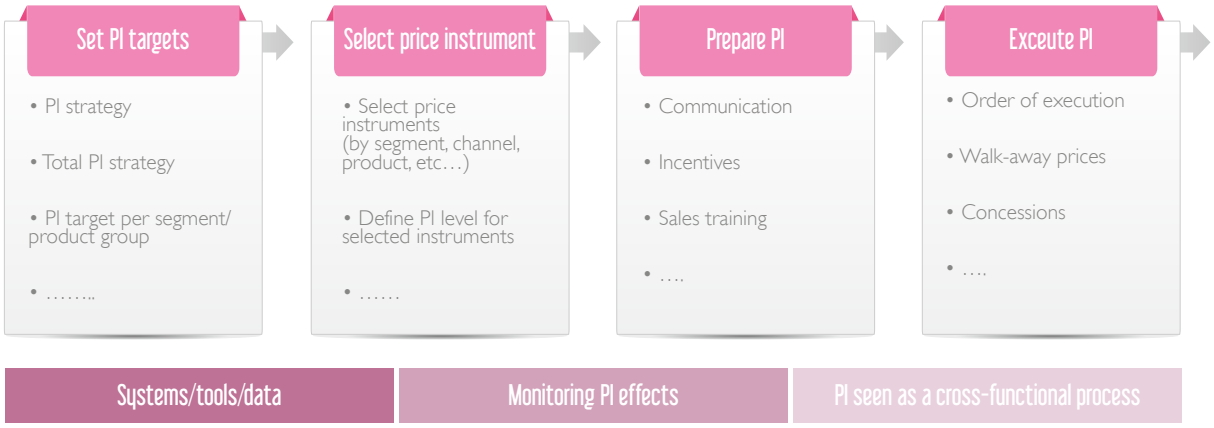
The pricing process involves several detailed steps and activities. Selected aspects – strategy and leadership, price instruments, and surcharges – are described below.

Strategy and leadership

Disproportionally small price increases do not work. We have seen and analyzed this more than a dozen times. **Companies often think they are extremely smart to pursue the following strategy:** They make smaller price increases than needed or than the competition is applying, then combine that with higher advertising spending, and hope for higher profits through high volume in shares. This strategy does not work out in reality. We have yet to see a single case in which this really led to success. Companies should not settle for lower prices; they must fight for the necessary increases. At the end of the day, volume and market share will not save you.

When it comes to price implementation, companies must know what their execution success rate is and set their price increase targets accordingly. It may sound easy to set price increase targets. The CEO calculates the cost increases, and that's what the sales team has to implement. In many cases it is really done that way. **But what is often forgotten is the price implementation or price execution success rate.** As companies achieve on average only half of their planned price increase, managers need to develop specific price increase targets by product, category, segment etc.

Price increases – a systematic process



Price instruments

Besides the classical list price increase, there are tens or perhaps even hundreds of price instruments available. The key is to go through the list of possible instruments, analyze which one fits your specific situation the best and then make a conscious decision as to which instruments to take – be it discounts, shorter payment terms, smaller package sizes and so on. Let's take a look at a package-size portfolio. The price of a one-liter bottle is known by many. Almost nobody overestimates it. Customers have a much lower price awareness of the small pack and more importantly, 50 percent overestimate the price. The solution is clear: Don't touch the one liter pack and apply a disproportionally high increase for the small pack. This is a general message that applies to B2B as well as B2C companies: **Different price increases by product/customer groups based on the level of price elasticity.**

Introducing a surcharge is another alternative. Many airlines have already gone too far with that instrument, but in other industries there is still a lot of potential. **Why do surcharges make sense?** Because the surcharge elasticity was and continues to be significantly lower than the elasticity of the base price. We don't suggest introducing surcharges across the board and blindly. The idea is to think broader, to be creative, and find price elements with high acceptance and low elasticity.

Preparation and communication is key

Companies often ask us whether they should be the first ones to make a price move. If a company is or wants to be the leader of an industry, then it must make the first move and set the anchor price. **Studies, scientists and Nobel Prize winners have revealed that nothing is more influential in determining the outcome as setting the initial price or, if you will, the anchor price.** As you can't be sure that your competition is doing the right thing, make sure that you are the first one to set and communicate the anchor. Many but still too few companies are doing that. When you knock at your client's door and ask for higher prices, the clients are already informed, they already know about the price change, and the bad news has already been communicated.

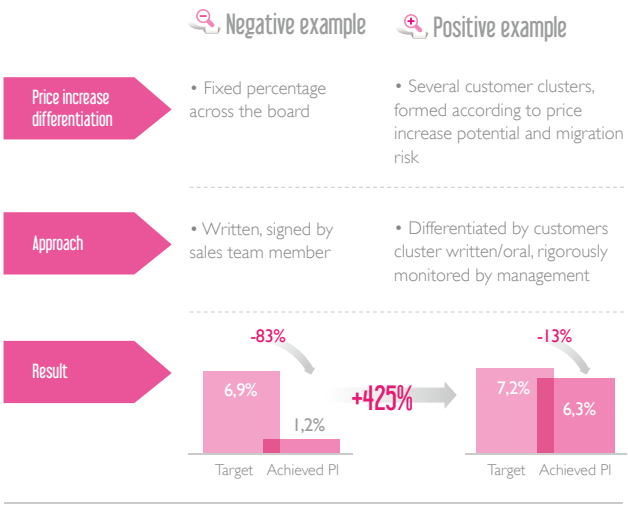
Execution and implementation

Price implementation is the job of sales. But it is also true that very often sales is struggling with this task. Either they only manage to implement a small part of the planned price increase or they give away goodies and discounts in exchange for the price increase; the bottom line is that nothing has been achieved. **What can be done to improve the price implementation?** We have had fantastic experience with simple on-top incentives — on top money that is only granted if certain price implementation targets have been achieved or overachieved. Let's take a concrete example. A sales rep had a revenue base of one million. He managed to raise the price by five percent, which was two percent points more than the minimum price increase target, in this case three percent. Two percent points means 20,000. Out of this 20,000 he got 25%, which is 5,000. The remaining part went to the company. The payout was on a quarterly basis, and only after the clients had paid their bills with the increased price levels. There was no negative cash effect for the company, no need for budgeting anything. That's a real a win-win situation. We applied it in a test group and this group achieved a 36 percent better price execution rate than the control group which did not receive any on-top incentive. In the meantime, we have implemented this type of incentives all over the world. It works everywhere. Some details have to be adjusted, but the principle is identical.

After having gone through the different steps of the process, we would like to underline once more that **this systematic approach not only pays off, but also is a must to achieve good results.** Look at these two

real case examples below. Both of them are in B2B business, the same industry, one followed the systematic process, the other announced the price increase and just scraped by. We have seen all detailed data of both companies, so we know that both were striving for a similar price increase: around seven percent. At the end of the day one achieved 1.2 percent, the other one 6.3. That is a plus of 425 percent. That clearly proves the success of a systematic approach.

Systematic preparation pays off



Recommendations and lessons learned

The study results reveal the formula for success: The better the pricing know-how, the higher the pricing power, and the higher the profits. Remember: At least 25 percent higher profits are proof enough. The five key recommendations are:

1. **Redirect your price strategy to achieve higher profits, rather than volume or market share. Introduce pricing power as a new KPI.**
2. **Pay particular attention to the pricing of new products and services.**
3. **Improve pricing expertise in sales, marketing and management.**
4. **Consider pricing implications already when developing new products**
5. **Make your company inflation-safe by improving your price implementation and setting high price increase targets.**

About the authors:

***Dr. Klaus Hilleke** is along with **Dr. Georg Tacke** CEO of Simon-Kucher & Partners Strategy & Marketing Consultants. Hilleke also heads the company's global life science division.* Robert Dumitrescu is Director in Simon-Kucher's life science division. The Global Pricing Study 2011 from Simon-Kucher & Partners surveyed over 3,900 high-level decision makers from companies in all major service and manufacturing industries across Europe, the US and Asia. The research reveals profit orientation, pricing power, inflation and profit outlook. Almost half of the respondents are from companies with more than one billion euros in sales; C-level executives account for one-third of the respondents. The study was conducted in collaboration with the Professional Pricing Society (USA) and the IE Business School (Spain).

CGF: concentrate growth factor from tissue regeneration

The ability to regenerate tissues and organs is a topic of great scientific, social and ethical interest.

Tissue engineering and regenerative medicine have made and continue to make great progress identifying new strategies in the field of tissue regeneration, such as the use of "platelet concentrate" which constitutes a relevant and innovative clinical approach.

From years Silfradent deals with the study of platelet concentrates and, in particular, with CGF (Concentrated Growth Factors) that represents a new generation of platelet concentrates able to hold inside a higher concentration of autologous growth factors.

CGF, like other platelet concentrates, is isolated from blood samples through a simple and standardized separation protocol, which is performed by a specific centrifuge device (Medifuge MF200, Silfradent srl, Forlì, Italy) without the addition of exogenous substances.

A study made in the "Laboratory of Organ and Tissue Regeneration", headed by Professor Luigi F. Rodella of the Section of Human Anatomy, Department of Biomedical Sciences and Biotechnologies of the University of Brescia and published in the international journal "Microscopy Research and Technique" has highlighted some of its main features: the CGF consists of an organic matrix rich in fibrin that is able to "trap" a greater amount of growth factors (TGF-ß1 and VEGF); moreover, it contains CD34 positive stem cells, which are known to be recruited from blood to injured tissue and play a role in vascular maintenance, neovascularisation and angiogenesis.[1] In addition, an other study underlined the need to establish a standardized protocol for preparing CGF (also said PRF-Platelet Rich Fibrin) membranes for clinical use.[2]

Form a clinical point of view, some recent studies about the use of CGF in maxillofacial surgery showed the efficacy of CGF in guided bone regeneration before dental implant placement.[3-5] In particular, there are satisfying results about the use of CGF as alternative to bone substitutes for sinus augmentation.[4,5]
However, its features make it suitable for its use, alone or with other biomaterials, in other fields where tissue regeneration and remodelling is required.
To date, the research continue and is addressed to evaluate "in vitro" the ability of CGF of stimulate cellular proliferation and to test the efficacy of CGF in different clinical applications ranging from oral surgery, dermatology and cosmetic surgery.

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