



## Medical Sector Economic Report

The area of medical technologies shows growth expectations of nearly the 4.6% for the next 5 years in the global market. This growth means an important challenge for the countries of the Latin American region with regards a renovation of the medical equipment in hospitals and surgery premises, as well as the need of innovations in their companies. In this region the local economies show, in general, sustained growth levels, being Argentina an example with a GPI growth of 9% for 2005 and, according to prestigious consultants, an expectation of 7%<sup>1</sup>.

To the growth rates shown in the different areas of the healthcare sector (larger or smaller according to the different countries) the constant requirements of both the professionals and patients involved have to be added, as they insist in assimilating the medical equipments used to those offered in the most developed countries (European Union, United States). Moreover, both in Europe and in Latin America, the tendency is to reduce the hospital stay (thus reducing the manpower requirements) which necessarily leads to investments in technology and equipments). The beneficiaries of the products of this sector are: hospitals, surgeries and homes, being the first the main consumer.

- The challenge of the Latin American sector of Medical Products and Equipment is not only the growth of both the production and the sales in the local market but also the internationalization of the medium and small companies. In this sense, we are dealing with a sector that in periods regularly favorable, has been able to develop a high standard local industry.

German companies will through a participation in ExpoMedical, establish cooperation links with local companies which have already developed proposals and products in the Latin American markets, transferring technology through joint ventures in a market with a sustained demand, and will position themselves more and more solidly in a market that has traditionally developed commercial interchange with the United States in detriment of the countries of the EU.

In this sector, the possibilities of establishing concrete commercial links between European and Latin American small and medium size companies are certainly varied and concrete in the short term.

The norms "Mercosur" (Common Market of the South that includes Argentina, Brazil, Paraguay and Uruguay) define Medical products as follows: « *It is a product for the healthcare such as equipment, device, matter, article or system for use or application in medicine, odontology or laboratory, whose destiny is the prevention, diagnostic, treatment, rehabilitation or anticonception, not using a pharmacological, immunological or metabolic means to carry out its function in human beings, but being it possible to be aided in its function by such means.*»

As it can be seen, the range of products related to the use and application of the healthcare is too wide, so we have limited the present project to the item "Medical Equipment" listing, just as example the following products:

- Electro medical equipment (Equipment for X-Rays, tomography, etc.)
- Implants
- Hospital and surgery equipment (equipment for pneumatology, anesthesiology, lamps, beds, etc)

<sup>1</sup> Source : Clarin, 31/12/2005, pág. 12 : Consultants quoted : Miguel Bein, 7,8% ; MVA, 7% ; Miguel Broda, 6,4%.

- Equipment for disabilities (e.g. wheelchairs, home care, hearing aids, etc)
- Equipment and products for ophthalmology
- Equipment for surgery and odontology
- Equipment for diagnostics
- Electronic medical equipment
- Anesthesiology
- Equipment, accessories and consumer goods for hemodialysis
- Equipment and devices for pharmacy and laboratory
- Others

#### **1.1.1.1. Position of companies of the sector in the sector in the countries involved**

**Argentina:** In the case of Argentina (being the site of ExpoMedical Argentina is the country represented by the majority of the participants), the sector has shown a continuous strengthening in the last years (after 2001/2002 crisis). There are factories that may result in potential partners of their European equals, basically due to their position in the local and regional market and for the possibilities in incorporating the state-of-the-art technology available for the European companies.

The market is made up of approximately 1/3 of manufacturing companies and the rest by importers and wholesalers of medical equipment. Although a number of 1500 companies are enrolled with the authorities, 1000 are the companies estimated to be operatively active nowadays, including manufacturers and wholesalers.

Most of them have developed international markets basically in the region, so they have the capacity and the will to incorporate quality standards compatible with those applied in first line countries in medical technology. It should be noted that in the MERCOSUR region, the tendency is to harmonize the normative, arriving to articles identical to those of the European Union, as a consequence of which the good practices of manufacturing (quality, security and efficiency) here required are similar to the other continent.

The high European quality levels are internationally recognized, to the point that in Argentina, a EU certification smoothens local inscriptions and registration of products. Although the great diversity of products manufactured can be considered a drawback, the existence of such niches and their specialization basically concentrated in small and medium size companies offer countless possibilities when we come to cooperation agreement between the two continents. On the other hand although Latin America has developed a local industry this has historically depended upon imported components to provide its markets. When harmonizing the normative with the international ones, the quality levels demanded will be similar to those in the countries with higher development in the sector.

It is an important point the knowledge of their respective local markets and the demand global tendency of high technology, among professionals and medical institutions (most of which is still using equipment that requires renovation). So joint ventures can be constituted with European partners of their respective niches in an important value in the projection of their business. In this way, both the transference of European technology as the constitution of a platform for Latin American markets (as importers distributors, etc) constitutes good expectations for the participating local companies.

#### **Target Market:**

**Argentina:** After the 2002 crisis, the sector started as recovery with a sustained growth of its levels of production, as well as that of the imports. The requirements for last technologies in

hospitals sustained and there is still much to do in order to renew the medical equipment in hospitals both public and private.

In this way 2004 exports reached the highest historical values (excepting 1995). Brazil in the first place and America constitute the main destiny of the said exports.

The imports (mainly high technology products) also present a sustained growth after the said crisis, reaching 500 million dollars the imports of the sector in analysis. In this case the country from which the imports originate in the first place is the United States (28,7%); Germany follows (10,7%) and then Brazil (9,3%). Italy has lost the third place in the ranking of the origin of the imports along the years. Se the following chart:

**Medical devices, for optics and precision and for watches**

**Structure and Evolution of the sector 1993-2004**

Index	Unit	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
1. Production (1)	1993=100	100,0	88,5	74,2	70,3	93,3	84,9	78,6	75,2	59,2	38,9	54,4	69,1
2. Foreign Trade													
2.1. Exports													
2.1.1. Values	Million USD	47,5	67,9	257,8	50,8	72,7	74,4	71,1	99,5	117,8	82,8	80,9	125,2
2.1.2. Expo / Production Gross Value <sup>(2)</sup>	%	8,1	13,4	61,8	12,3	13,0	14,5	15,1	24,0	38,8	58,7	39,0	47,0
2.1.3. Main Destinies	%	Brazil (24,6)	Suiza (55,3)	Suiza (50,3)	Brazil (25,3)	Brazil (33,0)	Brazil (23,0)	Brazil (30,5)	Brazil (43,8)	Brazil (45,6)	Brazil (40,5)	Brazil (42,3)	Brazil (38,5)
	%	México (14,2)	USA. (16,8)	USA. (37,2)	USA. (19,1)	USA. (14,8)	USA. (20,6)	USA. (19,8)	USA. (17,6)	USA. (12,7)	EE.UU. (13,1)	EE.UU. (8,3)	EE.UU. (11)
	%	España (11,4)	Brazil (6,3)	Brazil (2,6)	Chile (7,1)	Uruguay (7,4)	Chile (10,6)	Chile (8,0)	Chile (5,2)	México (5,6)	Chile (9)	Chile (8)	México (6,9)
2.2. Imports													
2.2.1. Values	Mill. de U\$S	473,8	645,0	556,2	648,7	799,3	788,4	713,8	721,1	577,8	207,1	341,5	497,2
2.2.2. Impto / Apparent consumption <sup>(2)</sup>	%	46,8	59,4	77,7	64,2	62,2	64,3	64,0	69,6	75,6	78,0	73,0	77,9
2.2.3. Main Origins	%	USA. (27,9)	USA. (33,4)	USA. (33,8)	USA. (33,9)	USA. (34,7)	USA. (33,1)	USA. (31,7)	USA. (35,6)	USA. (33,2)	USA. (31,8)	USA. (33,1)	USA. (28,7)
		Japón (10,7)	Alemania (9,6)	Alemania (11,1)	Alemania (9,5)	Alemania (8,3)	Alemania (8,0)	Alemania (8,9)	Alemania (9,1)	Alemania (10,4)	Brazil (13)	Alemania (1)	Alemania (10,7)

												0.5 )	
		Germany(10,3)	Italy(8,9)	Italy(7,2)	Italy(8,3)	Italy(8,3)	Japan(7,8)	Brazil(8,3)	Brazil(8,4)	Brazil(9,6)	Germany(9,7)	Brazil(10.1)	Brazil(9,3)

(1) Physical Volume Production

Index

(2) Due to the absence of data of Gross Production Value, it is estimated using data from the INDEC.

**SOURCE:**

[http://www.industria.gov.ar/cep/estsectorprodu/fichas\\_sectoriales.xls](http://www.industria.gov.ar/cep/estsectorprodu/fichas_sectoriales.xls)

In 2004 Argentina increased its imports in general coming from Europe. Among the most outstanding items are the instruments and devices for optics and medical surgical with a variation of 46% in 2003/2004. Of the total imports from the European Union this sector participates with a 4% (Source CEP based on INDEC). On the other side, the exports of micro and small exporters of this sector explain the 1% of the total valued in 3.3 million dollars FOB (source CEP on data base DGA).

If we limit ourselves to analyze the imports corresponding to a group of products of the sector (the most important: - Nomenclature 9018 a 9022), the following positive tendency that can be observed is that the market recovers after the 2001/2002 crisis (when analyzing the values it should be taken into account that the "convertibility" law that fixed 1\$=1USD and that favored the imports no longer exists)

Year	Total Imports Dollars FOB
1999	181.915.571
2003	86.541.625
2005	131.845.983
Source: Infojust	

From the said imports the largest volumes in dollars are those represented by the following products<sup>2</sup>:

Orthopedic products, probes, catheters and cannula, heart stimulators, ultrasonic exploration diagnostic devices, other medical, surgical and odontological devices and instruments, artificial kidneys, instruments and devices, electro diagnostic devices, hearing aids; automatic defibrillators, acicular prosthesis and other devices, oxygen therapy devices, respiratory reanimation devices, devices for respiratory therapies, blood pressure measurement devices, etc.

On an economic level, the activity branch that includes de sector threw a value of almost 500 million pesos in 2002.

***Incomes earned per activity branch in the manufacturing industry  
Year 2002 in thousand pesos***

<sup>2</sup> Source : Infojust

Activity branch Code	Activity Branch	Total
<b>D</b>	<b>General Level</b>	<b>158.298.969</b>
33	Manufacture of medical, optical and precision; watches	448.272
Source: INDEC, Annual Industrial poll		

Upon analyzing the healthcare sector (which demands the products of the sector selected) an important growth can be noted in the last years and the projection is to continue on this tendency. Thus, taking into account the number of medical establishments in the official sector, the general total of 6.193 in 1990 climbed to 8.075 in 2003.

<b>Healthcare Establishments in the official subsection – Total in Argentina Years 1990 / 2003</b>						
	<b>1990</b>			<b>2003</b>		
	<i>Total Gral.</i>	<i>W/beds</i>	<i>No beds</i>	<i>General Total</i>	<i>W/beds</i>	<i>No beds</i>
Total Argentina	<b>6.193</b>	1.179	5.014	8.075	1.319	6.756
<b>Source:</b> Healthcare Ministry. Secretary of Regulation Policies and Sanitary Relations. Direction of Statistics and Healthcare Information						

Out of a population of more than 36 million inhabitants, more than half enjoy the benefits of either trade union welfare plans or private healthcare plans (with the consequent impact in the demand of healthcare services and its impact in the sector).

**Total Population – Beneficiaries of trade union welfare plans or private healthcare plans, according to sex, and age groups  
Total del país. Año 2001**

Age group	Total	<b>trade union welfare plans or private healthcare plans</b>					
		Included in a plan			Not included in a plan		
		Total	Men	Women	Total	Men	Women
<b>Total</b>	<b>36.260.130</b>	<b>18.836.120</b>	<b>8.793.442</b>	<b>10.042.678</b>	<b>17.424.010</b>	<b>8.865.630</b>	<b>8.558.3</b>

Source: INDEC, Nacional Population Poll 2001.

**Business generation**

ExpoMEDICAL 2007 will offer the Latin American participating companies a valuable opportunity to generate agreements for the transference of technology, know how, economic cooperation and joint ventures with their European equals. Furthermore, there exist possibilities for economic complementation with some products that can be exported. On the side of European businessmen it is significantly attractive to find local partners in the Latin American markets (representatives and dealers) in order to foster and strengthen the position of their products. European companies will find an easier access to the markets where they have little or no presence at all through local representatives, dealers and importers.

**Competitive advantages and opportunities**

- The following can be listed as advantages for German companies participating at ExpoMedical:
  - They will start, or strengthen and increase their participation in the Latin American market of medical equipment, where other competitors already exist, (e.g. USA) with similar products which are already positioned.
  - They will find local partners with whom generate technological complementation agreements, making use of the competitive advantages that those agreements present, consolidating and improving the positioning of the European companies in the Latin American market dominated by other suppliers (mainly USA) and where European suppliers have even stepped backwards (e.g. Italy lost the third place in the origin of imports of medical products imports between 1994.1997 in favor of Brazilian and Japanese suppliers)

### **Justification of the election of the Fair and place**

Name of the Fair: Expo Medical

Organizer: Mercoferias SRL

City:Buenos Aires

Dates: 10 -12 September 2009

Sector: Products, Services and Equipment for the Healthcare Sector

Groups of products: Medical and Hospital equipment, medical consumer goods, hospital services, sterilization, electro medicine, X-rays and other image diagnostics, hospital bed, kitchen and laundry, hospital architecture and engineering, professional wear, healthcare and administration software, emergency and rescue, orthopedics and rehabilitation, products for the disabled, implants, professional furniture, products for odontology, laboratory and pharmacy, healthcare entities.

Number of exhibitors in last edition (2008): 200 (source: Official Catalogue)

Number of foreign exhibitors : 45 (source: Official Catalogue)

Number of countries participating with companies: 18

Net surface of stands in the last edition (2006): 11.500 m<sup>2</sup>

Number of visitors in the last edition (2006): 14.000

Web site of the Fair: [www.expomedical.com.ar](http://www.expomedical.com.ar)

E-mail address of the organizer [info@expomedical.com.ar](mailto:info@expomedical.com.ar)

### **Legal and normative aspects of interest for participating companies**

"In 1990, the European Union approved directive n° 385/CEE, which specifically regulates the active implantable cardiac medical products (pacemakers, implantable cardio defibrillators) and only in 1993 the Directive n° 93/42/CEE is published, establishing a general regulatory framework for the medical products, which only came fully into force 1998. The need to develop consistent and regimented concepts and criteria in this field encouraged the foundation of the Global Harmonization Task Force, GHTF, in 1992, a group of volunteers, representatives of the national regulating authorities and of the regulated industry of medical products. Since its creation GHTF has been integrated by representatives of its five founding members: the European Union, the USA, Canada, Australia, and Japan. The purpose of this organization is to promote the convergence of the regulatory practices related with the certainty of the security, efficiency, performance and quality of medical products, incentivating the technological innovation and thus providing the grounds for international commerce"<sup>3</sup>

<sup>3</sup> Source: Publication Consultor de Salud Nro. 37, P.4 – Technovigilance Programme, 1st . part - ANMAT

The MERCOSUR approved a body of rules and regulations aligned with the recommendations of the GHTF, which was progressively incorporated to the National Argentine normative between 1999 y 2004 (and which will be in full force in 2006).

In Argentina the normative revolves around two fundamental points:

- 1- Control of the manufacturing process and their complementary processes (importation, distribution, technical assistance, etc) and
- 2- Control of the devices design

There are two normative that regulate them fundamentally:

- a. The Rules and Regulations of Good Practices in the Manufacturing (Disp. 191/99-ANMAT) and
- b. The Rules and Regulations of Essential conditions of Security and Efficiency (Disp. 4306/99-ANMAT).

It should be pointed out that Argentine regulations follow the guidelines established by the GHTF and the European Union (Directive 9342CEE).

To market a product in Argentina (and similarly in the other countries of the Mercosur through their regional normative) the basic requirements are:

- 1- Compliance of the above mentioned System of Manufacturing Good Practices. In the case of manufacturers. In the case of manufacturers, the local authority, in this case ANMAT, will practice inspections at least every 5 years; manufacturers of certain recognized countries, as for instance those in the European Union, do not have to fulfill this requirement when presenting the certification of free sale in their country of origin.
- 2- Registration and habilitation of the company (manufacturer, importer, dealer, etc.).
- 3- Registration of the products ( national or imported) with a report according to the normative 3406/99 which is identical to that applied in Europe (Annex I of the Directive 9342CEE), where all the aspects related to the security and the efficiency of the product are listed.
- 4- In case the products originate from recognized countries (as in the case of the European Union ), the presentation of the certificate of free sale in the said countries will smooth the path for registration, as it will be presented together with the information that was presented in the country of origin according to the Annex I named before.

With respect to the importation of used medical equipment, in general it is only accepted for a small group of products (e.g. high technology image diagnostics equipment) and in these cases the importer will assume the responsibilities of the manufacturer before the local authorities.

As we have mentioned before, the normative in the European Union is practically identical to the Argentine normative, as the countries in the Mercosur have incorporated it almost textually to their local legislations.<sup>4</sup>

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<sup>4</sup> Fuente : ANMAT – Entrevista personal con Dr. Agustín Iglesias, Director de la Direcc. Tecnología Médica ANMAT  
Note of the Translator : ANMAT :(Argentine) National Food, Drug and Medical Technology Administration.