INFOMEDIX 1/2011 - INFODENT Srl - Strada Teverina km 3,6 Viterbo - Poste Italiane s.p.a. - Sped. in A.P. - D.L. 353/2003 (conv. In L. 26/02/2004 n°46) art. 1 comma 1 CB VITERBO - PP - ECONOMY - DCO/DCVT/ n°5fb - del 24/05/02 Contiene I.P.

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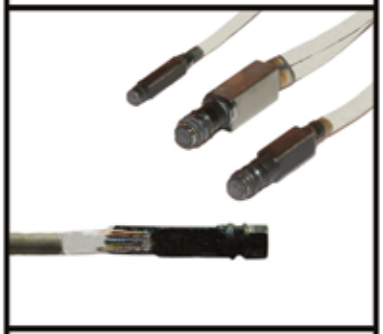

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Medical Market and Healthcare Reform In U.S.A

The USA represent the largest economy in the world, accounting for over 40% of the global consumer goods market, with a population of more than 300 million and approximately $48,000 per capita GDP…

El mercado de dispositivos médicos en los EE.UU. y la Reforma de Salud

Los EE.UU. representan la mayor economía del mundo, con más del 40% del consumo mundial de mercado de bienes, con una población de más de 300 millones y aproximadamente 48.000 dólares PIB per cápita...

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Cómo lograr una cobertura universal

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"Star Brace® Dynamyc Fix"

El nuevo concepto de Orliman en ortesis sacrolumbares con sistema modular

Permite diferentes opciones de inmovilización en el proceso de la recuperación. Un corsé revolucionario. Así puede describirse el "Star Brace Dynamic Fix", el último lanzamiento de Orliman, la reconocida marca valenciana de productos ortopédicos. Un concepto vanguardista que ha desarrollado su equipo de I+D+i y compuesto por una faja+módulo lumbar fabricado en termoplástico con placa abdominal. "Consiste en una ortesis sacrolumbar rígida fabricada en material transpirable bicapa compuesto en tejido de velour en poliamida e interior de tejido Poromax (que facilita la ventilación y la absorción de la humedad). A la vez incorpora un tratamiento anti-bacterias denominado "Thermy-tex", que evita el desarrollo de las bacterias causantes de malos olores", tal y como explica Juan Manuel Alba, Export Manager de Orliman.

Así mismo en la cara interior de la zona lumbar incorpora un módulo lumbar termoplástico premoldeado en polietileno de baja densidad el cual se fija mediante una funda textil que permite introducir o quitar el mismo. "Además en la cara exterior de la misma zona disponemos de un marco termoplástico provisto de un excepcional sistema de poleas, que ejercen sin esfuerzo la compresión selectiva de la zona lumbar y abdominal, a la vez que incluye en la zona abdominal por su cara interior una placa de compresión abdominal", añade el directivo.

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Quality Products at low prices

GPC Medical Limited, the best name in India in its field, is ISO 9001 & ISO 13485 certified, WHO–GMP compliant with a large number of CE Marked products. Orthopaedic Implants/Instruments and Hospital Furniture are the two most specialized product ranges. GPC is perhaps the first and the only Indian company whose bone plates and bone screws are US FDA 510(k) approved.

The other products, exported regularly in large quantities, against international bids also, include Anaesthesia Products, S.S. Hospital Holloware & Sterilizers, Autoclaves, Suction Units, Shadowless Lamps, Diagnostic Instruments, Weighing Balances, Microscopes, Cold Chain Equipment etc. The customer satisfaction at GPC, is achieved by supplying quality products at low prices within a short delivery time, paying due attention to packaging and packing.

There is hardly a country where the GPC products have not found their way. Many importers, particularly in European countries, even re-export the GPC products profitably.

For more information, please visit www.gpcmedical.com

Esxil Breast Forms

Fabricantes de Protesis Externas de Silicone

Exsil breast forms have been marketed for more than 10 years internationally under various trademarks and have proven quality and state of the art design. There is a two years limited warranty for all Exsil breast forms.

These are available in the most popular shapes such as the tear shape (above) and the triangle shape. The tear shape is particularly useful after total mastectomy, whereas the triangle shape is preferred for conservative surgeries. Both are available as an ultra light version, featuring a weight reduction of approximately 20 -25 compared to a regular breast forms.

For more information please visit: www.exsilbreastforms.net

EPIX SPIROL

Epidural Anesthesia Kit

AXEL is an Italian Company established in 2001 with more than ten years experience in the medical field achieved by its main members. Specific clinical areas of interest of our MEDICAL DEVICES are:

- Infusion Therapy
- Regional Anaesthesia-Pain treatment
- Oncology
- Dialysis

With a product portfolio composed by a large range of devices responding to most exigent requirements, AXEL main effort is concentrated to optimize all main critical points making the difference among the large market competitors such as: Quality, Pricing, Customization, with the main purpose of offering to our Clients their best synthesis.

Furthermore, thanks to our ability to cover the entire processes, from design to direct distribution of its products, AXEL has developed significant know-how in research and development of new products.
One of the new devices launched during MEDICA 2010 is our EPIX SPIROL: A kit for epidural anaesthesia with spiral reinforced catheter which is effectively implementing AXEL range for Anaesthesia/Regional Analgesia.

For more information visit.axel-med.com

Schulz Oil less compressor

When you think of health, confidence is key

Compressed air needs appropriate treatment for clinical procedures or human use. So you need a compressor to keep this standard: a Schulz Oil less compressor. The compressors of that line are compact, efficient, quiet and compatible with all kinds of equipment on the market.

The compressor pump, MSV 6/30 was specially developed for medical and dental applications, distinctively designed for use in the most demanding and rigorous bio safety and electro-mechanical safety areas. This compressor has anti-microbial internal and external painting and construction patterns in accordance with the highest worldwide standards.

Key benefits: oil less engine, with Teflon (PTFE) rings, anti-microbial additive painting, easy installation, tank and valves ASME approved and other international certificates.

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fabio.Lehn@schulz.Com.Br
Website: www.schulz.com.br

TINGET

Bringing the sterilization process to another level

DESCRIPTION:
We carried the sterilization process to another level with B type of TINGET's C series of autoclaves. This range of autoclaves has characteristics of high performance, reliability and safety. They are designed to completely meet EN13060.

FEATURES:
- Three times fractionated pre-vacuum.
- Temperature: 121 and 134 °C
- Pressure protection locking system.
- Overhead type water storage tank
- Sterilization cycles: 7 cycles are available and 3 test programs
- Test programs: Helix test, B&D test and Vacuum test
- Display: LCD screen
- Drying procedure: Dry by vacuum
- USB and Printer interface
- Independent steam generator
- Stainless steel chamber
- Warning system of Error codes
- Chamber capacity: 18L and 23L

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Web: www.tinget-autoclave.com

Mimosa- graduated compression hosiery

Innovation, the engine of our success.

Mimosa S.r.l. is a manufacturer of graduated compression hosiery. Sanyleg is the registered trademark by Mimosa to market its own products. Sanyleg is synonymous of elegance, comfort and - above all - well-being. This 100% Italian brand offers a full line of products designed for those who care about their leg health but who don't want to have to sacrifice beauty.

Products are scrutinised in almost craftsmanship-like detail, starting with the selection of prime raw materials. Sanyleg brings you a full range of hosiery: pantyhose, knee highs and therapeutic products that offer various degrees of compression.
Garments that guarantee the perfect fit that expert engineers and the right machinery can achieve.

Over 50 years of family experience in hosiery manufacturing has provided Sanyleg with the required experience to deliver the consistent and uncompromising quality for which its entire range is known. Each stage of the production process is performed in Italy. Sanyleg offers a wide range of products, from everyday-wear to medical items, not just dedicated to women: the unisex cotton line comprises hosiery and knee highs that are made with the same care and thoroughness that makes Sanyleg stand out above the rest.

Mimosa exclusively uses cotton from qualified Italian suppliers who provide only the best primary materials in order to maintain a perfect balance of comfort and well-being. Mimosa has been producing stockings with heels in partnership with the most prestigious brands for several years.

The company currently exports around 80% of its production to various countries all over the world: Germany, Japan, France, Switzerland, Austria, United Kingdom, Sweden, Turkey, Greece, Spain, Saudi Arabia, Iran, Sudan, Brazil, Argentina, USA and Australia.

Private Label's world market
Mimosa manufactures for major brands worldwide. Production capacity and value for money are the winning qualities behind "Private Label".

Mimosa has always made considerable room for its "Private Label" production, marketed throughout the world. This corporate decision has provided - and continues to provide - the opportunity to learn how to respond to the various and important customer needs by looking at the specific challenges and the different markets, cultures and particular requirements that involve on-the-spot assessment and production strategies.

Mimosa's strength lies in fact that it strives to consider and satisfy every customer requirement, customising products and producing "tailor-made" garments. Through direct consultation with clients, engineers and doctors, Mimosa is able to simultaneously address various issues and quickly come up with a solution. It is for this reason that most of the Mimosa production is developed under "Private Label" while the rest is marketed worldwide under the Sanyleg brand.

For more information visit www.sanyleg.com

HOSPITALAR: an important business and networking gathering for the entire healthcare chain

The leading fair of Brazil and Latin America will bring together in the city of São Paulo 1,250 exhibitors, from over 30 countries.

HOSPITALAR - 18th International Fair of Products, Equipment, Services and Technology for Hospitals, Laboratories, Pharmacies, Health Clinics and Medical Offices, the leading healthcare event in Latin America, will take place from May 24th to 27th, in the city of São Paulo, Brazil.

HOSPITALAR 2011 will feature 1,250 exhibitors from over 30 countries and will be spread over 82,000 sqm in the pavilions of the Expo Center Norte, introducing what is best in the healthcare world available for hospitals, clinics, laboratories and medical offices. HOSPITALAR will host around 89,000 professional visits during the four days of the event; including mostly hospital directors, nurses, doctors, distributors, manufacturers and international buyers.

The fair will bring together leading brands and the major decision makers of the healthcare chain. Says Dr. Waleska Santos, founder and president of HOSPITALAR: "The fair promotes business and fosters networking among the supplying industry and the directors of hospitals, clinics and healthcare professionals. HOSPITALAR is the most important meeting point of the hospital sector in Latin America".

The best in worldwide healthcare
Featuring very strong international characteristics, HOSPITALAR is currently a fully globalized fair, acting as a showcase for the healthcare world market.
The 2011 edition features over 500 foreign companies coming from the most diverse countries such as: Argentina, Austria, Belgium, Brazil, Canada, Chile, China, Czech Republic, Denmark, Egypt, Germany, France, India, Israel, Italy, Malaysia, Mexico, Pakistan, Portugal, Singapore, South Africa, South Korea, Spain, Switzerland, Taiwan, Turkey, United Kingdom, United States and Uruguay.

Visitors from 60 countries
Attendance of international buyers at HOSPITALAR grows year after year. The increasing number of international visitors confirms that the buyers regard the fair as an obligatory event in the world healthcare agenda.

HOSPITALAR also works as a business platform of the world suppliers for the leading Latin American buyers. Just to mention: out of the 15 countries with enhanced representativeness among the visitors at the last edition, 12 were from Latin America: Argentina, Brazil, Peru, Chile, Colombia, Bolivia, Paraguay, Uruguay, Venezuela, Mexico, Ecuador and Costa Rica.
However, the area of influence of the event is much bigger, a fact that has been proved by the diversity of the visiting countries: Angola, Canada, China, Czech Republic, France, Finland, USA, Germany, Indonesia, Iran, North Korea, Pakistan, Russia, Saudi Arabia, UK and many more.

Major forum of the healthcare management
HOSPITALAR is also acknowledged as the most important forum of healthcare in Latin America, bringing together Brazilian and foreign leaders to discuss new concepts in healthcare management. The fair features about 60 events that include congresses, seminars, workshops and trade meetings, focusing management and optimization of the financial and human resources of the healthcare establishments.

SERVICE
Hospitalar 2011 - 18th International Fair of Products, Equipment, Services and Technology for Hospitals, Laboratories, Pharmacies, Health Clinics and Medical Offices
Date: 24 to 27 May 2011 – from 12:00 noon to 09:00 pm
Venue: Pavilions of the Expo Center Norte - Rua José Bernardo Pinto, 333 - Vila Guilherme - São Paulo – Brazil

FIME 2011: This Is Your Chance To Shine

FIME is the Largest International Medical Trade Fair and Congress in the United States. FIME 2011 is going to take place from 10 until 12 August in Miami Beach Convention Center.

Registrants from around the world and from all specialties and disciplines of the total health care arena attend FIME to see the latest medical equipment, products, supplies, technology and services and learn from industry experts in the three-day, five track educational conference.

Companies exhibit at FIME primarily to generate high volume sales. The annual event is a purchasing show catering to conventional distributor networks, group purchasing organizations, integrated delivery networks, hospitals, imaging centers, private practice facilities, and HME/DME providers.

The dynamic attendee base is key to penetrating and navigating around complicated medical distribution channels and networks.
Exhibit floor focused, FIME flat-out gets products to market.
Held annually for the last 21 years in Miami Beach, one of the top international destinations in the world and the absolute hub for business in North, South and Central America.

Considering that the United States health care market accounts for 41% of the global total and South and Central America is the home of 7 major rapidly growing markets this is a must visit show! FIME offers exhibitors a convenient, comfortable and safe environment to do business with medical buyers from across the globe.

For more information please visit www.fimeshow.com

Huge interest and new participants in Bulmedica/ Buldental

The most prestigious medical exhibition in South East Europe BULMEDICA/BULDENTAL, held under the auspices of the Ministry of Health in Bulgaria, has attracted Bulgarian and foreign companies' huge interest again.

Health experts are eagerly awaiting the 45th edition of the exhibition and the organisers are reminding that the international exhibition will be held from 17th to 20th of May, 2011.
The host Inter Expo Centre – Sofia is ready to meet not only regular participants – producers and commercial companies of products, technics and equipment from Bulgaria, Slovakia, Czech Republic, South Korea, China and others but also new participants from Germany, Poland, Italy, Russia, Sweden, Austria and other countries.

Prestigious medical companies from the Czech Republic have chosen to participate jointly for the third year in a raw. There will be national participation of companies from South Korea which will show their products in the medicine and dental part of the exhibition.

Medical and dental companies from Italy and Sweden will participate jointly for the first time. The exhibition halls of BULMEDICA will turn into modern health and hospital centres equipped with the latest models of clinic and laboratory equipment, ordinary and specialized furniture, instruments, reagents, materials and other products for treatment and medical services.

Technics and aids for disabled persons, physiotherapy and rehabilitation will be among the exhibits. Innovations in dental medicine have their influence upon BULDENTAL scales. More and more producers, commercial companies and dealers of dental equipment and furniture, apparatuses, instruments, materials and consumables for dental treatment and dental technics are taking part in the exhibition.

BULMEDICA/BULDENTAL again will draw the professionals' attention to issues concerning the humane and dental medicine, and the health care systems in the country as a whole.
The Bulgarian Medical Association will focus on important issues of organ donation, transplantations, emergency aids at a specialised conference.
Professionals from hospitals, non-hospital treatment centres, diagnose and consulting centres, medical and dental clinics will have the opportunity to attend lectures, practical courses, seminars and presentations of technics and equipment for the health care which will be held during BULMEDICA/BULDENTAL.

Following the tradition that started the last year, poster session of the participants in the upcoming edition of the national competition Smile of the Year will be arranged within the exhibition frameworks. The joint initiative is realized by Dental Tribune Newspaper as organizer of the competition and Bulgarreklama Agency as organizer of BULMEDICA/BULDENTAL.

For additional information, visit www.bulmedica.bg

Why Syrian Medicare 2011

After ten years of continous success, Syrian Medicare chain has become a Medicare distinct to meet and achieve the increasing demands and requirements, by highlighting the latest recent developments in medical science in various fields, the event is also considered an effective marketing tools by meeting the relevant specialized customer directly (Exporters, Importers, Doctors, Decision Makers, Businessmen, and all relevant medical personnel).

Medicare chain has not only been able to introduce new leading medical equipment companies for the Syrian and regional medical markets, but also the show used to ensure the attending of the most Ideal and professional medical visitors.
In this regards, the last event has witnessed remarkable success by registering professional medical visitors as follows:

- Total Number of visitors	4630	100 %
- Professional:	4096	88 %
- Others:	534	12 %
- Domestic:	4230	91 %
- Arab & Foreign:	400	9 %
- Countries:	17	

(Italy, India, Tunis, KSA, Iraq, Iran, Cyprus, Lebanon, Egypt, Jordan, Libya, Canada, Pakistan, Sudan, Yemen, Turkey, UAE)
- Official Delegations: 2
(Spanish delegation in cooperation with FENIN Association and Tunisian Delegation)

Syrian Medicare 2010 has covered over 8.000 sqm in space area and hosted more than 415 international companies and brand names from 40 countries through 145 exhibitor companies, as well as 50 international direct participation companies from 12 countries not represented by any local agent and searching for real local partners in the Syrian market coming from Belgium, Taiwan, Egypt, China, Turkey, Italy, Germany, Pakistan, Austria, India, Jordan, Lebanon and Syria.

SYRIAN MEDICARE CHAIN 2011: This year Syrian Medicare 2011 will host the Turkish National Participation for the third time, which will showcase the latest technologies and systems in the medical and healthcare industrial fields, in addition to a group of Taiwanese companies and Iranian companies, and other medical & pharmaceutical equipments' companies coming from China, India, Germany, Italy, Egypt, Pakistan ,France , UK, Belgium & Lebanon. Beside the participation of the biggest Syrian medical local companies and agents.

For more information visit www.syrianmedicare.com

MEDICAL FAIR THAILAND 2011

MEDICAL FAIR THAILAND will have its 5th presentation in Bangkok, Thailand, from 14 to 16 Sept 2011.

The exhibition will provide vital access for companies trying to penetrate the Southeast Asian markets. The combined population of Southeast Asia which is in excess of 540 million people, the changing demographics, longer life expectancy and the aging population will have an enormous impact on the need for better healthcare. In addition, with the increase in foreign patients, particularly in Thailand, many of the healthcare institutions are in need of new equipment, devices, solutions and better technologies to serve the medical and healthcare needs.

MEDICAL FAIR THAILAND is pleased to bring together the best in the business of hospital, diagnostic, pharmaceutical, medical and rehabilitation equipment and supplies to Thailand and the neighbouring Southeast Asian countries. MEDICAL FAIR THAILAND will also serve as a platform for medical suppliers, industry professionals, government bodies, hospital administrators, doctors, nurses and other healthcare professionals.
5,000 trade visitors and buyers from the region are expected to visit the 3-day exhibition. Join us in bringing global and healthcare technologies to one of the most dynamic regions in the world.

For more information please visit www.medicalfair-thailand.com

CHINA SOURCING FAIR: Medical & Health Products October 20-23, 2011, AsiaWorld-Expo, Hong Kong

Keep your medical & health products up to date with the latest from China

China Sourcing Fair: Medical & Health Products returns this autumn to provide you with another strategic China sourcing in Hong Kong. Source the latest and affordable products in the industry at AsiaWorld-Expo on October 20 to 23, 2011.

The recently concluded inaugural Fair in spring this year welcomed thousands of buyers in search of practical sourcing solutions from China. With China Sourcing Fair's reliable assembly of competitive and export-oriented suppliers, plus 100% industry-specific exhibits, visitors made new connections and found the latest products relevant to their business.

The autumn 2011 Fair will showcase new product advancements in these categories:
Dentistry equipment & supplies
Health & wellness
Medical care & supplies
Medical equipment & emergency products
Rehabilitation & physiotherapy supplies

Source with confidence from competitive suppliers
The China Sourcing Fair boasts Hong Kong's biggest group of Chinese manufacturers who remain at the forefront of global trade industry as they provide reasonable price points and flexible delivery terms. Choose your next suppliers from hundreds of Fair exhibitors from mainland China, Taiwan and Hong Kong. Plus, widen your product search with more suppliers from other emerging Asian supply hubs.

Source with convenience at AsiaWorld-Expo
Only a minute from the Hong Kong Int'l Airport and less than an hour from downtown Central via Airport Express train, the world-class AsiaWorld-Expo is the most convenient sourcing venue in Hong Kong. The venue is also equipped with modern facilities guaranteed to make your sourcing more productive.

Gain more from free on-site features
More than providing you with quality sourcing, the China Sourcing Fair also features complimentary on-site services to make your visit more rewarding. Hear China sourcing tips at the Conference Program and Ask the Experts. Relax at the Wine & Cappuccino Bar or check your email at the Buyers' Lounge.

Make the smart move to boost your business with strategic China sourcing now! Sign up online for your free China Sourcing Fair entry badge at www.chinasourcingfair.com

Medtrade Spring Expo to Feature Thousands of Products, Networking Opportunities

ALPHARETTA, Ga.—March 10, 2011—Home medical equipment providers from across the country will meet at Medtrade Spring 2011 to seek new products directly related to improving the care of their patients and the success of their businesses.

Medtrade Spring, the home medical equipment industry's mid-year event, will take place April 12 – 14 at the Sands Expo and Convention Center in Las Vegas. The event is owned and produced by Nielsen Expositions. This year's Expo will showcase the latest technological advancements in home medical equipment. Over 300 exhibitors will be on hand to meet with attendees, debut new products and offer creative solutions for managing business operations. In addition to the Expo, Medtrade Spring will offer a strong educational program and numerous networking events.

Now more than ever, it is essential that providers utilize the cost-effective opportunities that Medtrade Spring provides. The ongoing collaboration between Medtrade and AAHomecare make it the perfect venue to develop effective strategies to current legislative challenges, says Kirsten DeLay, executive vice president of sales management and operational planning for Pride Mobility Product and chair of Medtrade's Blue Ribbon Task Force. The value of meeting with exhibitors and learning about new product and business solutions makes a trip to the show a worthy investment. The continually expanding educational opportunities alone make Medtrade a very efficient means of keeping your business ahead of the curve.

In addition to the thousands of products, the Expo will feature: The Medtrade Spring New Product Pavilion The State Association Pavilion. The Medtrade Spring Beer Garden and Networking Reception, sponsored by Infopia USA

The value of industry shows where the HME provider has the opportunity to network with other providers and see new products and programs to help them maximize their profits only happens a few times a year. Medtrade Spring is one of those opportunities. It would be a shame not to take advantage of it, says Ron Bendell, president, VGM & Associates. Special registration rates for the Expo and Medtrade Spring Educational Conference are in effect until March 14. All registration information can be found at medtrade.com.

Nielsen Expositions upcoming health care events include Medtrade Spring 2011, which will take place April 12 – 14 at the Sands Expo and Convention Center in Las Vegas, and Medtrade 2011, which will take place at the Georgia World Congress Center in Atlanta on October 24 – 27. For more information about the events, please visit medtrade.com or call (800) 933-8735.

KIMES 2011 Propels Medical Industry Ahead

Korea has a large, diverse and vibrant medical device manufacturing industry which has boomed with the rapid growth of the country's economy in the past two decades or so.

The large scale of the medical industry has been very much in evidence at KIMES (Korea International Medical and Hospital Equipment Show). The show has fulfilled high expectations with the newest medical products. To present the opportunity experiencing various and latest medical developing, the 27th KIMES took place at COEX in Seoul from 17-20 March, with hundreds of manufacturers showcasing their products.

Recently, Korea medical industry has been developed from the center of disease treatment to the enlargement of medical service and healthcare quality to expand its level to an advanced country. Also, we are facing a great opportunity of outer expansions such as increasing exports, diversification of product, and etc. by localization of knowledge intensive high-tech medical equipment based on IT. For a instance, portable diagnosis devices treatment are showcased which provides reduction of time spending and place limit. Furthermore, through remote digital diagnosis system, a patient can possibly be received consultation.

The unique 27th KIMES 2011 was the direction for the latest medical technology through well over than 1,026 companies from 32 countries with local 453 manufacturing companies. It was a valuable time to see all leading, high-technology medical, eco-friendly products and diverse solution being evolved by convergence between IT and medical technology.

The medical industry is one of the leading industries that would drive the Korea economy in the future. To stimulate this growth the government provides a blue print for political and financial support of the industry. KIMES has received strong support from various government bodes including Ministry of Knowledge Economy, Ministry of Health, Welfare and Family Affairs, Seoul Metropolitan Government, and Korea Food & Drug Administration.

The range of exhibits at KIMES included 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.

There was a balance between the different exhibition categories, as KIMES is a total healthcare related show. While it is important to include innovative new technologies, involving digitalisation and personalisation, it is also important that KIMES shows the direction in which the entire industry is heading.

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The medical device market in the USA and the Healthcare Reform

The USA represent the largest economy in the world, accounting for over 40% of the global consumer goods market, with a population of more than 300 million and approximately $48,000 per capita GDP. The average disposable income of US citizens is about $35,000. A leading exporting economy, the USA have established Free Trade Agreements with 17 partner countries with a combined GDP of over $5.1 trillion.

The US market for medical devices was estimated at about $94.9 billion in 2010, making it the largest medical market in the world. According to the US Department of Health & Human services, average per capita health spending was $8,086 in 2009, totaling $2.5 trillion and accounting for 17.6% of GDP.

El mercado de dispositivos médicos en los EE.UU. y la Reforma de Salud

Los EE.UU. representan la mayor economía del mundo, con más del 40% del consumo mundial de mercado de bienes, con una población de más de 300 millones y aproximadamente 48.000 dólares PIB per cápita. El ingreso disponible promedio de los ciudadanos de los EE.UU. es de aproximadamente $ 35.000. Una economía exportadora líder, los EE.UU. han establecido acuerdos de libre comercio con 17 países socios con un PIB combinado de más de 5100 mil millones de dólares.

Los EE.UU. representan la mayor economía del mundo.

El mercado de los EE.UU. para los productos sanitarios se estima en alrededor de 94,9 mil millones de dólares en el 2010, convirtiéndose en el mayor mercado de la medicina en el mundo. De acuerdo con el Departamento de Servicios Humanos y de Salud de los EE.UU, el promedio de gasto per cápita en salud fue 8.086 dólares en el 2009, un total de 2,5 trillones 500.000 millones de dólares y representa el 17,6% del PIB.

Healthcare provision is essentially based on private or employer-sponsored insurance plans without any single public health system. The government runs two insurance programs for elderly, disabled and lower income people, known as Medicare and Medicaid. Medicare provides health insurance for people age 65 or older, people under age 65 with certain disabilities, and people of all ages with End-Stage Renal Disease. It covers inpatient and outpatient care and prescription drugs. Medicaid is available only to low-income individuals and families who meet some eligibility requirements set by federal and state law, although each state sets its own guidelines regarding eligibility and services.

Medicaid pays for medical services of the covered patients directly to the health care providers, but depending on each state's rules, a small part of the cost is covered by co-payments for some medical services. Medicare covers 44 million Americans and accounts for 14% of the federal budget, while Medicaid accounts for 7%.

Medicaid is the largest payer for long-term care, covering 41% of all long-term care costs. Medical expenses are a serious concern for American households, as rising insurance premiums as well as common insurance companies' practices such as denial of coverage or higher premiums charged on people with previous illnesses, have long severely impacted on the ability of large groups of the population to have adequate access to healthcare.

For instance, according to the Kaiser Family Foundation, since 1999 family premiums for employer-sponsored insurance have increased 138%, while wages have gone up 42% and inflation has gone up 31%. Because of escalating healthcare costs, money that would have gone to wage raises has instead been spent on health premiums that have doubled over the past nine years. The Foundation reports that in 2009, 50 million nonelderly people in the United States lacked health coverage in 2009, 77% of which come from working families and 69% are from the low-income group. About 83% of the nonelderly uninsured in this group were adults aged 19-64 who are generally ineligible for public coverage and often unable to get a private insurance, but also 8.3 million children lacked health coverage in the same year.

> Medical expenses are a serious concern for American households

La prestación de asistencia sanitaria se basa fundamentalmente en planes de seguro privado o financiados por el empleador sin ningún tipo de sistema de salud pública. El gobierno tiene dos programas de seguro para ancianos y para la población con discapacidad y de bajos ingresos, conocidos como Medicare y Medicaid. Medicare provee seguro de salud para personas de 65 años o más, las personas menores de 65 años con alguna discapacidad, y personas de todas las edades con enfermedad renal en etapa terminal. Abarca la atención ambulatoria y medicamentos con receta médica. Medicaid está disponible sólo para personas de bajos ingresos y las familias que cumplan con algunos requisitos de elegibilidad establecidos por la ley federal y estatal, aunque cada estado establece sus propias directrices relativas a la elegibilidad y los servicios.

Medicaid paga por los servicios médicos de los pacientes cubiertos directamente a los proveedores de atención de la salud, pero dependiendo de las normas de cada estado, una pequeña parte del costo es cubierto mediante los co-pagos para algunos servicios médicos. Medicare cubre 44 millones de estadounidenses y representa el 14% del presupuesto federal, mientras que Medicaid cubre el 7%.

Medicaid es el mayor contribuyente para el cuidado a largo plazo, cubriendo el 41% de todos los costos de cuidado a largo plazo. Los gastos médicos son una seria preocupación para los hogares estadounidenses, el aumento de las primas de seguros, así como otras prácticas comunes de las compañías de seguros, tales como, la negación de la cobertura o el cobro mayor de primas a las personas con enfermedades anteriores afecta gravemente desde hace mucho tiempo, la capacidad de los grandes grupos de la población a tener acceso adecuado a la atención sanitaria.

Por ejemplo, según la Fundación de la Familia Kaiser, desde 1999 las primas familiares de los seguros financiados por el empleador han aumentado un 138%, mientras que los salarios han subido un 42% y la inflación ha subido un 31%. Debido a los crecientes costos de salud, el dinero que habría ido a aumentos salariales en cambio, ha sido dedicado a las primas de salud que se han duplicado en los últimos nueve años. La Fundación señala que en el 2009, 50 millones de personas que no son ancianos en los Estados Unidos carecían de cobertura médica, el 77% de los cuales provenían de familias trabajadoras y el 69% eran del grupo de bajos ingresos. Cerca del 83% de los no asegurados que no son ancianos eran los adultos de edades entre 19 a 64 años que eran generalmente inelegibles para la cobertura pública y, a menudo no podían obtener un seguro privado, pero también 8.3 millones de niños carecían de cobertura médica en ese mismo año.

BMI
BIOMEDICAL INTERNATIONAL

your reliable partner

Our range of products include:

- Mobile radiographic units for bedside examinations;
- Mobile C-arms for orthopaedics-cardiology-surgery and interventional radiology;
- 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

Visit our website www.bmibiomedical.it
Meet us at:

ARAB HEALTH ECR MEDICA

BMI Biomedical International s.r.l.
Via E. Fermi 52 Q/R
24035 Curno (BG) - Italy

On March 23, 2010, President Obama signed the healthcare reform bill officially known as "Patient Protection and Affordable Care Act", introducing comprehensive health insurance reforms to be implemented in the course of the next few years (the last provision is scheduled to come into force in 2018), aiming at extending health insurance coverage to an estimated 32 million Americans currently lacking any form of health insurance. The health reform was subject to an heated debate which is still going on, concerning among the other issues its consequences on the public budget and on the medical device industry competitiveness in technological innovation.

Among the points brought forward from the supporters of the reform there are the broader scope of publicly insured people, increased protection towards US citizens who were until now rejected by insurance companies because of previous illnesses or poor health status, incentives for small businesses to provide health insurance for their employees, increased competition and stronger regulations for private insurance companies, and in the long term, more efficiency due to a quality- rather than service-based compensation for medical services.

Some of the major changes introduced by the ACA with direct or indirect effect on the medical industry include:

- Increased funding to community health centres for infrastructure improvements ($727 million) and expansion of medical services ($335 million).
- Comparative Effectiveness Research establishing a non-profit Patient-Centered Outcomes Research Institute to conduct research that compares the clinical effectiveness of medical treatments.
- Extended dependent coverage for adult children up to age 26 for all individual and group policies, with effect for new plans and existing plans by renewal on or after September 23, 2010.

On March 23, 2010, President Obama signed the healthcare reform bill

El 23 de marzo de 2010, el presidente Obama firmó el proyecto de reforma de salud conocido oficialmente como "Protección de Pacientes y Ley de asequible atención de la salud" (Patient Protection and Affordable Care Act, ACA), introduciendo amplias reformas a los seguros de salud, las cuales se aplicarán en el curso de los próximos años (la última disposición está programada para entrar en vigor en 2018), pretendiendo ampliar la cobertura de seguros de salud a un estimado de 32 millones de estadounidenses que carecen actualmente de cualquier forma de seguro de salud. La reforma de salud fue objeto de un acalorado debate que está todavía en curso, relacionado entre otros temas con las consecuencias sobre el presupuesto público y en la competitividad en la innovación tecnológica de la industria de dispositivos médicos.

Entre los puntos presentados por los partidarios de la reforma están: el ámbito más amplio de personas aseguradas públicamente, una mayor protección a los ciudadanos de EE.UU. que eran hasta ahora rechazados por las compañías de seguros debido a enfermedades previas o mal estado de salud, los incentivos para las pequeñas empresas para proporcionar seguros de salud para sus empleados, el aumento de la competencia y una regulación más estricta de las compañías de seguros privadas, y a largo plazo, una mayor eficiencia debido a la calidad en lugar del servicio basado en la compensación por los servicios médicos.

Algunos de los principales cambios introducidos por la ACA que tienen efectos directos o indirectos en la industria médica incluyen:

- *Aumento de la financiación de los centros de salud comunitarios para mejorar la infraestructura (727.000.000 dólares) y la expansión de los servicios médicos ($ 335 millones).*
- *Investigación de la eficacia comparativa, estableciendo un Instituto de Investigación de Resultados centrado en el paciente sin fines de lucro para llevar a cabo la investigación que compara la eficacia clínica de tratamientos médicos.*
- *Cobertura dependiente extendida para hijos mayores de edad hasta los 26 años para todas las pólizas grupales e individuales, a partir de los nuevos planes y los planes existentes renovados a partir del 23 de septiembre 2010.*
- *Crédito fiscal para pequeñas empresas, proporcionando créditos a los pequeños empresarios con no más de 25 empleados y el salario medio*

• Small Business Tax Credits, providing tax credits to small employers with no more than 25 employees and average annual wages of less than $50,000 that provide health insurance for employees. In the period 2010-2013, tax credit will be brought up to 35% (25% for non-profits) of employer cost; from 2014 on, tax credit will go up to 50% (35% for non-profits) of employer cost if purchased through an insurance Exchange for two years.
• Annual Fees on the pharmaceutical manufacturing sector from January 1, 2012.
• Excise tax of 2.3% on the sale of any taxable medical device from January 1, 2013.
• Individual requirement to US citizens and legal residents to have health insurance coverage, with tax penalties for those without coverage, from January 1, 2014.
• Creation of state-based Health Benefit Exchanges and Small Business Health Options Program (SHOP) Exchanges, through which individuals and small businesses with up to 100 employees can purchase qualified coverage, from January 1, 2014.

anual de menos de $ 50,000 que brindan seguro de salud para los empleados. En el período 2010-2013, el crédito fiscal se elevará al 35% (25% sin fines de lucro) de los costos del empleador, a partir de 2014 en adelante, el crédito fiscal se elevará de hasta un 50% (35% para organizaciones no lucrativas) de los costos del empleador si se compran a través por medio de un intercambio de seguro por dos años.
• *Las tasas anuales en el sector de fabricación de productos farmacéuticos desde 1 de enero de 2012.*
• *Impuesto selectivo al consumo del 2,3% sobre la venta de cualquier producto sanitario sujeto a impuestos desde 1 de enero de 2013.*
• *Requisitos individuales a los ciudadanos de EE.UU. y los residentes legales a tener cobertura de seguro de salud, con penas de impuestos para los que no tienen cobertura, el 1 de enero de 2014.*
• *Creación de un programa del estado basado en las opciones de intercambios de beneficios y pequeñas empresas de la Salud. (SHOP) Intercambios a través de los cuales los individuos y pequeñas empresas con hasta 100 empleados pueden comprar cobertura cualificada, del 1 de enero de 2014.*

According to a recent report by the firm Zacks Equity Research (Medical Devices Industry Outlook – April 2011), the proposed tax on device companies, the increased regulatory scrutiny and the less flexible pricing environment are pointed out as potential factors of uncertainty for medical devices companies, especially the small and medium sized enterprises that constitute the majority of the manufacturing sector. It is a controversial issue to determine what the effect of the reform might be on the medical industry, one of the few domestic industries that showed a positive trade export of over $5billion over the past few years. As the US medical technology industry needs to maintaining its highly competitive, leading role in innovation and research, it is crucial to evaluate the impact of the new system on this capability.

Según un informe reciente de la firma de Zacks Equity Research (Industria de Dispositivos Médicos Outlook - abril 2011), el impuesto propuesto a las compañías de dispositivos, el control normativo y ambiente menos flexible de precios, son señalados como posibles factores de incertidumbre para las empresas de productos sanitarios, especialmente la pequeña y mediana empresa que constituyen la mayoría del sector manufacturero. Se trata de una cuestión controversial el determinar cuál será el efecto que la reforma podría tener en la industria médica, una de las pocas industrias nacionales que mostraron una exportación comercial positiva de más de $ 5billion en los últimos años. A medida que la industria de la tecnología médica estadounidense necesite para mantener su altamente competitivo, el papel de liderazgo en la innovación y la investigación, es crucial evaluar el impacto del nuevo sistema en esta capacidad.

Se trata de una cuestión controvertida para determinar cuál es el efecto de la reforma podría estar en la industria médica.

Many start-up companies resort to the Small Business Innovation Research programme to get their funding, but private funding through venture capital has become the main source of investment in medical technology innovation, attracted by the possibility of reimbursement from public health programmes and commercial insurers. However, the more cautious approach to analysis and approval of medical devices adopted by the FDA and the effects of the comparative effectiveness research on reimbursement policies are expected to affect the ease of introducing innovative technologies.

Market profile

The US have a strong domestic production of medical devices, equipment and products, exceeding $100 billion. The medical device manufacturing sector is diversified and technologically advanced, with significant developments in fields such as neurology, cardiology, health IT and minimally invasive surgery. Traditionally a country with high investments rates in medical device R&D, the economic downturn impacted on the health and medical technology research that totaled $139 billion in 2009, growing by only 0.1% over 2008.

Medical device companies are spread everywhere across the country, but there is a concentration of high-tech clusters on the East coast (New York, Pennsylvania, Massachusetts, Georgia, Florida), and also in the States of California, Michigan, Illinois and Minnesota. Many of the world's leading medical device manufacturers, such as Johnson & Johnson, General Electric, Baxter, Covidien and Medtronic are US-based, and seven out of the world's top ten device manufacturers are US companies.

The main sectors of the medical industry (based on NAIC classification) are surgical appliances and supplies (28% of the total Value of Shipment, VOS), surgical and medical instruments (26% VOS), electro-medical equipment (19% VOS), in-vitro diagnostic substances (10% VOS) and irradiation apparatuses (8% VOS), while dental and ophthalmic equipment and products both account for approximately 5% of the total VOS. The USA are the world's largest exporter of medical devices,

> The USA are the world's largest exporter of medical devices, for a total value of more than $36 million in 2009

for a total value of more than $36 billion in 2009. In his remarks at AdvaMed 2010 Medical Technology Conference, Commerce Secretary Gary Locke pointed to China, India, Brazil, South Korea and ASEAN countries as the key markets addressed by the US medical industry. He estimated that US medical exports to China, that exceeded $1.2 billion in 2009, are going to increase by 5-10% annually over the next five years, boosted by healthcare reforms and expansion of health insurance. Export growth is expected also towards India, as it already increased by 12% at compounded annual growth rate (CAGR) over the last decade, given the demand for high-quality products by a growing middle class of about 300 million people disposing of rising incomes.

Brazil's CAGR for medical imports exceeded 20% in the period 2004-2009, although the country's programs in support of the domestic industry is likely to impact on US exports. The South Korean market is valued at $3 billion in 2010 and several ASEAN countries are planning to modernize their healthcare systems, at the same time experiencing CAGR of over 10% in the past five years, which makes them interesting markets for US companies.

Muchas empresas de nueva creación recurren al Programa de investigación novedosa para las pequeñas empresas para obtener su financiamiento, pero la financiación privada por medio de capital de riesgo se ha convertido en la principal fuente de inversión de la tecnología médica de innovación, atraídos por la posibilidad de reembolso de los programas de salud pública y las aseguradoras comerciales. Sin embargo, el enfoque más prudente para el análisis y aprobación de productos sanitarios aprobados por la FDA y los efectos de la investigación comparativa de la efectividad de las políticas de reembolso se espera que afecten a la facilidad de en la introducción de tecnologías innovadoras.

Perfil del Mercado

Los EE.UU. tienen una fuerte producción nacional de dispositivos sanitarios, equipos y productos, de más de $ 100 mil millones. El sector de fabricación de dispositivos médicos es diversificado y tecnológicamente avanzado, con importantes avances en campos como la neurología, cardiología, salud de TI y la cirugía mínimamente invasiva. Tradicionalmente un país con altas tasas de inversión en equipo médico de investigación y desarrollo, en el cual la crisis económica impactó en la investigación de la tecnología médica y de salud que llegó a $ 139 millones en 2009, creciendo sólo un 0,1% respecto al 2008.

Las empresas de productos médicos se distribuyen por todo el país, pero hay una concentración de alta tecnología en la costa este (Nueva York, Pennsylvania, Massachusetts, Georgia, Florida), y también en los estados de California, Michigan, Illinois y Minnesota. Muchos de los principales fabricantes de dispositivos médicos del mundo, tales como Johnson & Johnson, General Electric, Baxter, Covidien y Medtronic tienen sede en Estados Unidos, y siete de los diez principales fabricantes de dispositivos del mundo son compañías de EE.UU.

Los principales sectores de la industria médica (basado en la clasificación NAIC) son aparatos ortopédicos y suministros (28% del valor total del envío, VOS), quirúrgicos e instrumentos médicos (26% VOS), aparatos electro-médicos (19% VOS), sustancias de diagnóstico in vitro (VOS% 10) y los aparatos de irradiación (8 VOS%), mientras que equipos dentales y oftalmológicos representan aproximadamente el 5% del total de VOS.

Los EE.UU. son el mayor exportador mundial de productos sanitarios, por un valor total de más de $ 36 millones en 2009. En su discurso en la Conferencia de Tecnología Médica de AdvaMed del 2010, el secretario de Comercio Gary Locke señaló a China, India, Brasil, Corea del Sur y países de la ASEAN como los mercados clave que aborda la industria médica de los EE.UU. El estimó que las exportaciones médicas de EE.UU. a China, que superaron los $ 1.2 mil millones en 2009, van a aumentar en un 5-10% anual durante los próximos cinco años, impulsado por las reformas de salud y la ampliación del seguro de salud. Se espera también el crecimiento de las exportaciones hacia la India, debido a aumento de un 12% de la tasa de crecimiento anual compuesto (CAGR) durante la última década, dada la demanda de productos de alta calidad por una clase media cada vez mayor de aproximadamente 300 millones de personas que disponen de ingresos en aumento.

La tasa de crecimiento anual compuesto de Brasil para la importación médica superó el 20% en el período 2004-2009, aunque los programas de apoyo del país a la rama de producción nacional es probable que impacten a las exportaciones de EE.UU. El mercado de Corea del Sur es un valor de $ 3 mil millones en 2010 y varios países de la ASEAN tienen previsto modernizar sus sistemas de salud, al mismo tiempo que experimentan una tasa de crecimiento anual compuesto de más del 10% en los últimos cinco años, lo que los convierte en mercados interesantes para empresas de EE.UU.

On the import side, there has been an increase in the value of imported medical devices principally in lower technology products segments such as surgical gloves and instruments. While exports in this category grew by 61.5% from 2002 to 2007, imports more than doubled over the same period, as it also happened to imports of dental equipment. Imports are currently accounting for about 30% of the total market, partly because of US manufacturers using cheap locations abroad, such as Ireland or Mexico, in order to re-export to the US market. Any foreign manufacturing firm wishing to import a medical device or radiation-emitting product into the US must comply with FDA regulatory requirements. FDA does not recognize regulatory approvals from other countries.

According to the US International Trade Administration, as reported in its "Medical Device Industry Assessment" (March 2010), the US market is highly regulated, and it can be an expensive one in which to operate, but it is transparent and 'rules-based'. Distribution and post-sales assistance needs to be carefully planned in the different States in order to compete with local companies on the huge US territory. Hospitals are the largest end-users of medical equipment and are constantly seeking cost-containment in their purchases. However, the growth of outpatient care centres such as ambulatory surgical centres, diagnostic imaging and rehabilitation centres are broadening the market scope. Home care is a promising sector as the pressure for health expenditure reduction and population ageing is encouraging delivery of healthcare at home with a broad and increasing offer of high-tech medical devices to be used by the patient and the nursing staff. Moreover, Health IT is being targeted by the governmental Stimulus Package to incentivize hospitals and medical practitioners to use electronic health record systems.

Las importaciones actualmente representan alrededor del 30% del total del mercado, debido parcialmente a que los fabricantes de EE.UU utilizan lugares baratos en el extranjero como Irlanda o México, con el fin de re-exportar al mercado de EE.UU.

Por el lado de las importaciones, se ha producido un aumento en el valor de los dispositivos médicos importados principalmente en segmentos de productos de menor tecnología, tales como guantes quirúrgicos e instrumentos. Mientras que las exportaciones de esta categoría crecieron un 61,5% desde el 2002 hasta 2007, las importaciones se duplicaron durante el mismo período, como también sucedió a las importaciones de equipos dentales. Las importaciones actualmente representan alrededor del 30% del total del mercado, debido parcialmente a que los fabricantes de EE.UU utilizan lugares baratos en el extranjero como Irlanda o México, con el fin de re-exportar al mercado de EE.UU. Toda empresa de fabricación extranjera que desee importar un producto o dispositivo sanitario que emita radiación a los EE.UU. deben cumplir con los requisitos reglamentarios de la FDA. La FDA no reconoce las aprobaciones regulatorias de otros países.

De acuerdo con la Administración de Comercio Internacional de los EE.UU., como se informó en su "Evaluación de la Industria de Dispositivos Médicos" (marzo 2010), el mercado de EE.UU. está muy regulado, y puede ser caro operar en el, pero es transparente y basado en reglas. La distribución y la asistencia posterior a las ventas debe ser cuidadosamente planificada en los diferentes Estados a fin de competir con las empresas locales en el gran territorio de los EE.UU. Los hospitales son los mayores usuarios finales de equipos médicos, y están constantemente buscando la contención de costos en sus compras. Sin embargo, el crecimiento de los centros de atención ambulatoria, tales como centros de cirugía, de diagnóstico por imagen y centros de rehabilitación están ampliando el alcance del mercado. La atención domiciliaria es un sector prometedor ya que la presión para reducir de los gastos innecesarios en salud y el envejecimiento de la población está alentando a la entrega de la asistencia sanitaria en casa con una amplia oferta y un aumento en la oferta de servicios médicos de alta tecnología para ser utilizados por el paciente y el personal de enfermería. Por otra parte, Salud TI está siendo dirigida por el paquete de estímulos gubernamentales para incentivar a los hospitales y los médicos a usar los sistemas electrónicos de registro médico.

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www.medicaldevice-network.com

Fuentes:
Departamento de Salud y Servicios Humanos de EE.UU. (http://www.hhs.gov; www.healthcare.gov)
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Outlook on Latin America

Perspectivas para América Latina

The LatIn American region experienced a remarkable economic growth in the last few years, but the global recession slowed it in 2010. Healthcare provision in the Latin American countries presents a gap between the high quality care available in the private sector and the uneven access to basic healthcare services for lower income groups.

The total market for medical devices is valued at US$8.1 billion. Mexico is the largest medical market, followed by Brazil, Venezuela and Colombia. Only Mexico and Brazil have established a developed regulatory system, although the Brazilian model has influenced the medical regulations in MERCOSUR countries leading to an increased harmonisation. Mexico, on the other hand, is closer to the US FDA's regulations.

La región de América Latina experimentó un crecimiento económico notable en los últimos años, pero la recesión mundial desaceleró su crecimiento en el 2010. Las prestaciones de asistencia sanitaria en los países de América Latina presentan una brecha entre la atención de alta calidad disponible en el sector privado y el acceso desigual a los servicios de atención básica de salud para las personas que tienen mas bajos ingresos.

El mercado total de productos sanitarios tiene un valor de 8.1 mil millones de dólares. México es el mercado médico más grande, seguidos por Brasil, Venezuela y Colombia. Sólo México y Brasil han establecido un sistema de regulación desarrollados, aunque el modelo brasileño ha influido en las normas de medicina en los países del MERCOSUR que conduce a una mayor armonización. México, por el contrario, está más cerca a los reglamentos estadounidenses del FDA.

Imports are the main source of medical equipment and supplies in almost any Latin American country except for Brazil where a relevant share of equipment is supplied by the local industry. A different composition of medical imports is also present, as Brazil, Argentina and Chile are more oriented towards importing medical technology products while Peru, Mexico and Venezuela import more consumables. Mexico accounts for most of medical exports, basically for US manufacturers 'maquiladora' activities by assembling or manufacturing in a local factory for re-export. A relevant volume of exports also comes from Brazil but it is still low compared to the size of its medical market.

MEXICO

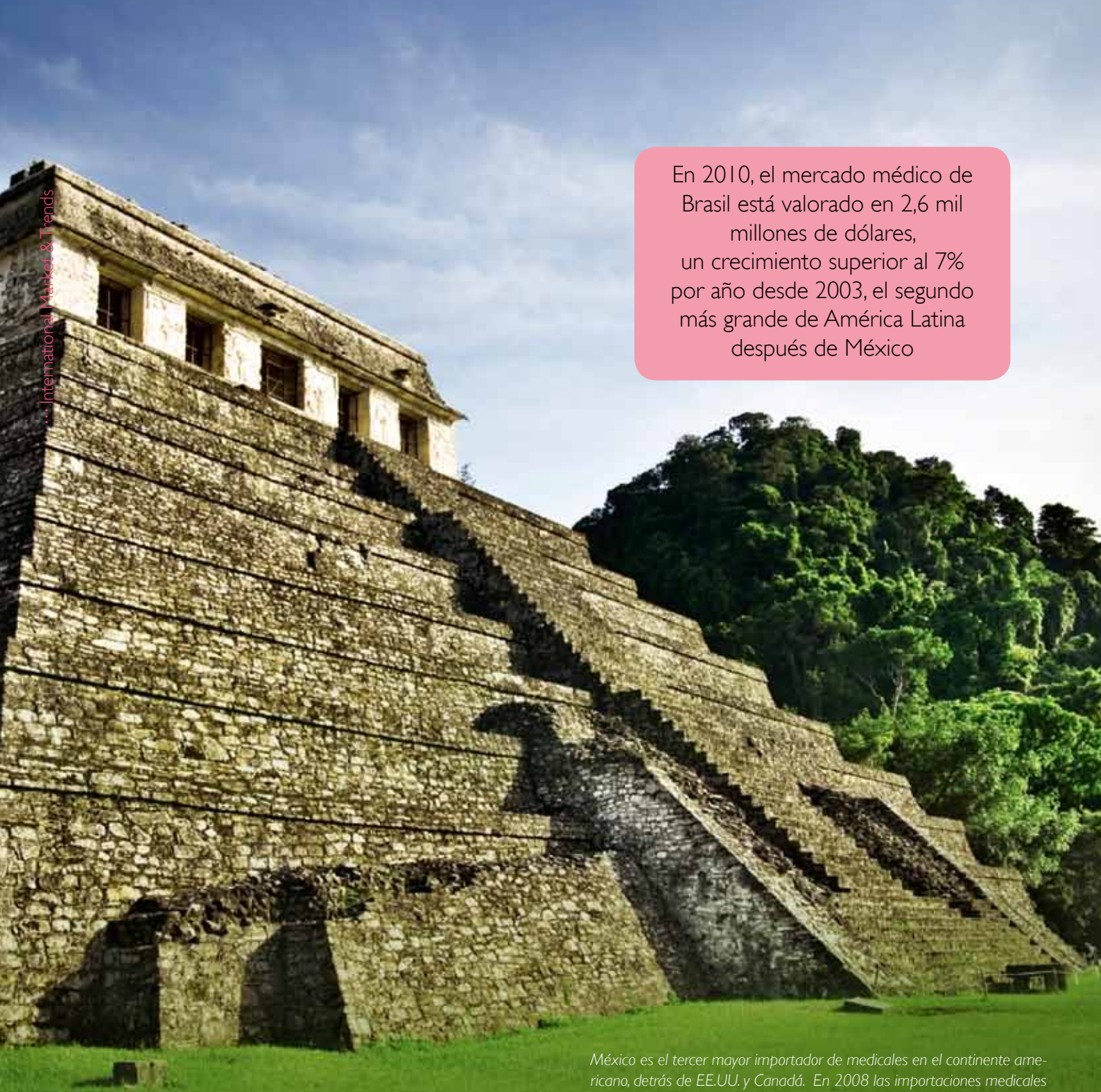
The market for medical devices is estimated at US$2.7 billion in 2010, the largest in Latin America. Health expenditure valued at US$61.7 billion in 2008, of which US$29.1 billion came from public expenditure (around 47.1%), however per capita expenditure is relatively low. Public expenditure on the poorer, uninsured groups rose 20.6%, compared to spending on the insured (6.8%). The public sector is contributing to market growth by investing in hospital and new technology acquisition, particularly in diagnostic & orthopaedic equipment. Some medium and small private hospitals with limited budgets buy used or refurbished equipment, but public hospitals are not allowed to. Public institutions can purchase up to US$3,100 directly from a selected provider, over that amount they must purchase through public tenders.

> Mexico is the largest medical market, followed by Brazil, Venezuela and Colombia

Las importaciones son la principal fuente de equipos y suministros médicos en casi cualquier país de América Latina a excepción de Brasil donde una relevancia de equipos es suministrada por la industria local. Hay una composición diferente de importaciones médicales también como en Brasil, Argentina y Chile que están más orientados hacia la importación de tecnología de productos médicos, mientras que Perú, México y Venezuela importan más insumos. México representa la mayor parte de las exportaciones de productos medicales, fundamentalmente por las actividades de 'fabricantes' maquiladoras EE.UU. para la reexportación. Un volumen relevante de las exportaciones también proviene de Brasil, pero siguen siendo bajas en comparación con el tamaño de su mercado médico.

MÉXICO

El mercado de los productos sanitarios se estima en 2.7 mil millones de dólares en 2010, el más grande de América Latina. El gasto en salud está estimado en un valor de 61,7 mil millones de dólares en 2008, de los cuales 29,1 mil millones de dólares EE.UU. provenía de gasto público (alrededor de 47,1%), sin embargo el gasto per cápita es relativamente bajo. El gasto público en los grupos de personas más pobres y sin seguro aumentó en el 20,6%, en comparación con el gasto de los asegurados (6,8%). El sector público está contribuyendo al crecimiento del mercado mediante la inversión en el hospital y en la adquisición de nueva tecnología, especialmente en equipos de ortopedia y de diagnóstico. Algunos pequeños y medianos hospitales privados con presupuestos limitados compran equipos usados o reconstruidos, pero los hospitales públicos no se les permite. Las instituciones públicas pueden comprar hasta un valor de 3.100 de dólares directamente desde un proveedor seleccionado, mientras que por un valor mayor de esto debe ser comprado a través de licitaciones públicas.



En 2010, el mercado médico de Brasil está valorado en 2,6 mil millones de dólares, un crecimiento superior al 7% por año desde 2003, el segundo más grande de América Latina después de México

Mexico is the third largest medical importer in the Americas, behind the USA and Canada. In 2008 medical imports reached US$2.5 billion, 51.1% of which come from the US due to geographic proximity and NAFTA agreements. Some of these imports, however, are destined to maquiladora activities whose products are sent back to the USA. Imports supply 90% of the Mexican market for medical equipment and instruments, and 20% of demand for medical disposables. Besides the US, other suppliers are Belgium, Brazil, Canada, China, France, Germany, Israel, Italy, Japan, Netherlands, South Korea and UK. As for medical exports, in 2008 they were valued at US$5.2 billion, 91.7% of which was directed towards the USA, while EU-27 accounted for 7.1%. Consumables are the major export area, followed by orthopaedic & implantable products.

México es el tercer mayor importador de medicales en el continente americano, detrás de EE.UU. y Canadá. En 2008 las importaciones medicales alcanzaron los 2.5 billones de dolares, el 51,1% de los cuales provienen de los EE.UU. debido a la proximidad geográfica, y a los acuerdos del TLCAN. Algunas de estas importaciones, sin embargo, están destinados a las actividades de las maquiladoras, cuyos productos son enviados de regreso a los EE.UU.. Las importaciones suministran el 90% del mercado mexicano para los equipos e instrumentos médicos, y el 20% de la demanda de productos médicos desechables. Además de los EE.UU., otros proveedores son Bélgica, Brasil, Canadá, China, Francia, Alemania, Israel, Italia, Japón, Países Bajos, Corea del Sur y el Reino Unido. En cuanto a las exportaciones de productos médicos, en 2008 alcanzaron un valor de 5,2 mil millones de dólares el 91,7% de los cuales estaba dirigida hacia los EE.UU., mientras que los a la UE-27 representaban el 7,1%. Los consumibles son la mayor área de exportación, seguido por implantables y productos ortopédicos.

Following the New Health Accord of 25th November 2010, medical devices already approved and commercialised in the USA and Canada will be evaluated and authorised by COFEPRIS (Federal Commission for the Protection against Sanitary Risk) within 30 days from the date of importer's notification to the Mexican health authority. All medical equipment and devices with a NAFTA certificate of origin can be imported duty free. Imports are subject to a 15% VAT tax over the invoice value.
Medical and health care products need to be registered with the Mexican Secretariat of Health (SSA) prior to sale or use in Mexico. Some medical products need to comply with technical standards or NOMs (Norma Oficial Mexicana) based on the Harmonized System Code (HS). Foreign manufactures must appoint a distributor/representative in Mexico that is responsible for the registration process.

BRAZIL

Brazilian population reached 190 million people in 2010, and is growing by 1.2% annually. 84% of the population live in urban areas, where higher healthcare expenditure is also registered. In 2010 the Brazilian medical market is valued at US$2.6 billion, growing more than 7% per year since 2003, the second largest in Latin America after Mexico.

Recognized by the WHO as the second major medical technology provider among emerging countries, Brazil has a strong domestic medical production boosted by domestic demand for healthcare services and government investments in the health sector. In fact, in the period 2003-2010 Brazil invested more than US$ 28 million in medical equipment, basically in innovation projects and laboratories for product certification. However, imports have increased at a CAGR of 28% between 2004 and 2008, and represented 45.5% of the 2009 domestic consumption, while exports represented 14% of the national production. The Brazilian health sector has still a negative trade balance with US$ 2.2 billion shortage registered in 2009, although the national industry is potentially capable of covering 90% of the demand for hospital equipment. Only the dental sector registers a commercial surplus. Implants increased by 7.7% in external sales in 2009 compared to 2008, while on imports' side, radiology imports increased 8.5% followed again by implants with 8.3% growth. USA were the main buyer (25.8%) and the main supplier (33.1%) of consumables, equipment and materials used in the Brazilian dental, medical-hospital and lab segments in 2009.

A raíz del Acuerdo por la Nueva Salud del 25 de noviembre de 2010, los productos sanitarios ya aprobados y comercializados en los EE.UU. y Canadá serán evaluadas y autorizadas por la COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios) dentro de un plazo de 30 días a partir de la fecha de la notificación de la autoridad sanitaria mexicana. Todos los equipos y dispositivos médicos con un certificado de origen del TLCAN se pueden importar libres de impuestos. Las importaciones están sujetas a un impuesto del 15% de IVA sobre el valor de la factura.
Productos medicales y de salud deben estar registrados en la Secretaría Mexicana de Salud (SSA) antes de su venta o su uso en México. Algunos medicamentos deben cumplir con las normas técnicas o NOM (Norma Oficial Mexicana), basado en el Sistema de Código Armonizado (SA). Manufacturas extranjeras deben designar a un distribuidor o representante en México, que es responsable del proceso de registro.

BRASIL

La población de Brasil alcanzó los 190 millones de personas en 2010, y está creciendo en un 1,2% anual. El 84% de la población vive en zonas urbanas, donde hay un gasto mayor en la salud social. En 2010, el mercado médico de Brasil está valorado en 2,6 mil millones de dólares, un crecimiento superior al 7% por año desde 2003, el segundo más grande de América Latina después de México.

Reconocida por la OMS como el segundo mayor proveedor de tecnología médica entre los países emergentes, Brasil tiene una fuerte producción médical nacional impulsada por la demanda interna de los servicios de salud y las inversiones del gobierno en el sector de la salud. De hecho, en el período 2003-2010 Brasil invirtió más de 28 millones de dólares en equipos médicos, fundamentalmente en proyectos de innovación y laboratorios de certificación de productos. Sin embargo, las importaciones han aumentado en un CAGR de 28% entre 2004 y 2008, y representó 45,5% del consumo nacional de 2009, mientras que las exportaciones representaron el 14% de la producción nacional. El sector salud de Brasil aún tiene una balanza comercial negativa con 2,2 mil millones de dólares escasez registrada en 2009, aunque la industria nacional es potencialmente capaz de cubrir el 90% de la demanda de equipos hospitalarios. Sólo el sector dental registra un superávit comercial. Los implantes aumentaron en un 7,7% de las ventas externas en 2009 en comparación con 2008, mientras que por el lado de las importaciones, las de radiología aumentaron en un 8,5% seguido de nuevo por los implantes con el 8,3% de crecimiento. EE.UU. eran el principal comprador (25,8%) y el principal proveedor (33,1%) de los consumibles, equipos y materiales utilizados en el mercado dental brasileño, médico-hospitalarios y en los segmentos de laboratorio en 2009.

More than 2,000 companies sell medical products and equipment in Argentina, of which 25% are manufacturers and 75% importers

Domestic	Consumption Data 2009 in US$ thousands
Invoicing of the sector	3,864,575
Total imports	2,772,865
Total exports	541,110
Apparent consumption	6,096,330

Source: Brazilian Medical Devices 2010/2011 (based on data from ABIMO/SECEX)

Doméstico	Consumo de datos 2009 en miles de dólares
Facturación del sector	3,864,575
Importaciones totales	2,772,865
Exportaciones totales	541,110
Consumo aparente	6,096,330

Fuente: Brazilian Medical Devices 2010/2011 (sobre la base de datos de ABIMO / SECEX))

The medical sector accounts for 0.47% of Brazilian economy, a relevant figure considering the relatively small number of companies active in the sector compared to the number of companies in the whole country's industry (about 300,000). In the last 11 years, the medical sector grew 37% in terms of companies, but the total invoicing had a 306.7% increase from almost US$1.2 million in 1999 to US$ 4.6 billion in 2009, attesting their growth in the market.

The concentration of the 448 medical companies is higher in Southeast and South regions of the country, especially in Sao Paulo with 86% of all companies (40% out of which are located in the capital, Sao Paulo). South region has 12% of companies, mainly located in the state of Paraná. The medical-hospital sector generates about 31,800 direct employs and companies produce 71% of items in their own factories, while importing 12% from headquarters. 91% of companies operate with national capital while 9% with foreign capital. In mixed-capital companies, average participation of national capital is 52%. More than half of foreign companies operating in Brazil are from USA and Germany.

El sector médico cubre uno 0,47% de la economía brasileña, una figura relevante considerando el número relativamente pequeño de empresas que operan en el sector en comparación con el número de empresas en todo el país (unas 300.000). En los últimos 11 años, el sector médico aumentò en un 37% en términos de empresas, pero la facturación total tuvo un incremento de 306,7% desde casi 1.2 millones de dólares en 1999 a 4,6 mil millones de dólares en 2009, lo que demuestra su crecimiento en el mercado.

La concentración de las 448 compañías médicas es mayor en las regiones Sudeste y Sur del país, especialmente en Sao Paulo con 86% de todas las empresas (40% de los cuales están ubicados en la capital, Sao Paulo). En las Regiones del Sur hay un 12% de las empresas, principalmente en el estado de Paraná. El sector médico-hospitalario genera cerca de 31.800 empleados directos y las empresas producen el 71% de los artículos en sus propias fábricas, mientras que la importación es de un 12% procediente de la sede. El 91% de las empresas operan con capital nacional, mientras que 9% de capital extranjero. En el capital de empresas mixtas, la participación de capital nacional tiene una media del 52%. Más de la mitad de las empresas extranjeras que operan en Brasil son de EE.UU. y Alemania.

ARGENTINA

Argentina is the fourth largest country in Latin America, with a large elderly population. The market has recovered since the 2002 economic crisis, although the total market size has decreased in dollar terms due to the devalued peso. More than 2,000 companies sell medical products and equipment in Argentina, of which 25% are manufacturers and 75% importers.

ARGENTINA

Argentina es el cuarto país más grande en América Latina, con una gran población de adultos mayores. El mercado se ha recuperado desde la crisis económica de 2002, aunque el tamaño total del mercado ha disminuido en términos de dólares, debido a la devaluación del peso. Más de 2.000 empresas venden productos y equipos médicos en la Argentina, de los cuales 25% son fabricantes y un 75% son importadores.

The medical manufacturing sector provides low- to medium-tech equipment, supplying many domestic healthcare needs, while imports accounted for approximately $515 million in 2008, where diagnostic reagents and clinical lab represented over $250 million and the dental market about $25 million.

The demand for middle and high-end technology products such as implants, stents, cardiac valves, pacemakers, specialized disposables, lab equipment, imaging diagnostic equipment, medical ultrasound and electrocardiograph equipment is mainly met by imports, accounting for around 70-75% of the total market. Components and electro-medical equipment parts are also required due to the broad need, particularly in the interior provinces, for reconditioning rather than replacement of equipment already in use.

Imports are exempt from import duty under Mercosur. However, US leads the import sector with 28% market share, particularly in high-end technology products, with 14% growth in 2010. Other countries supplying medical equipment and products are Germany (11.2%), Japan (9.1%) and China (7%).

El sector manufacturero médical provee a los equipos de baja y media tecnologia, suministrando muchas de las necesidades de salud nacional, mientras que las importaciones representaron aproximadamente $ 515 millones en 2008, donde los reactivos de diagnóstico y los productos para laboratorio clínico representan más de $ 250 millones y el mercado dental alrededor de $ 25 millones.

La demanda y la tecnología de los productos de gama medio-alta, tales como implantes, prótesis, válvulas cardiacas, marcapasos, desechables especializados, equipos de laboratorio, equipos de imagen de diagnóstico, el ultrasonido y equipos médicos electrocardiográficos es fondamentalmente cubierto por las importaciones, que representan alrededor del 70-75% del mercado total. Componentes y piezas de equipos electro-médical también son necesarios debido a la amplia necesidad, sobre todo en las provincias del interior, para el reacondicionamiento en lugar de sustitución de equipos ya en uso.

Las importaciones están exentas de derechos de importación dentro del Mercosur. Sin embargo, EE.UU. lidera el sector de importación con una cuota de mercado del 28%, sobre todo en la tecnología de los productos finales de alta tecnologia medical, con un crecimiento del 14% en 2010. Otros países que suministran equipos médicos y otros productos son Alemania (11,2%), Japón (9,1%) y China (7%).

Tamaño del mercado Médico, en miles de dolares estadounidenses

	2009	2010	2011 (aprox.)
Tamaño total del mercado	694,900	778,400	801,800
Producción local total	290,000	275,500	283,800
Exportaciones totales	96,800	83,300	85,800
Importaciones totales	501,700	586,200	603,800

Fuente: Guía de Recursos de Tecnologías de la Salud 2009-2010

Medical market size, US$ thousands

	2009	2010	2011 (est.)
Total Market Size	694,900	778,400	801,800
Total Local Production	290,000	275,500	283,800
Total Exports	96,800	83,300	85,800
Total Imports	501,700	586,200	603,800

Source: Healthcare Technologies Resource Guide 2009-2010

Sources:
U.S. Commercial Service Global Healthcare Technologies Team: Healthcare Technologies Resource Guide 2009-2010 Edition (www.export.gov)
Espicom Business Intelligence: The Outlook for Medical Devices in Latin America to 2015 (www.espicom.com)
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Revista Hospitais Brasil / Editora Publimed: Brazilian Medical Devices 2010/2011

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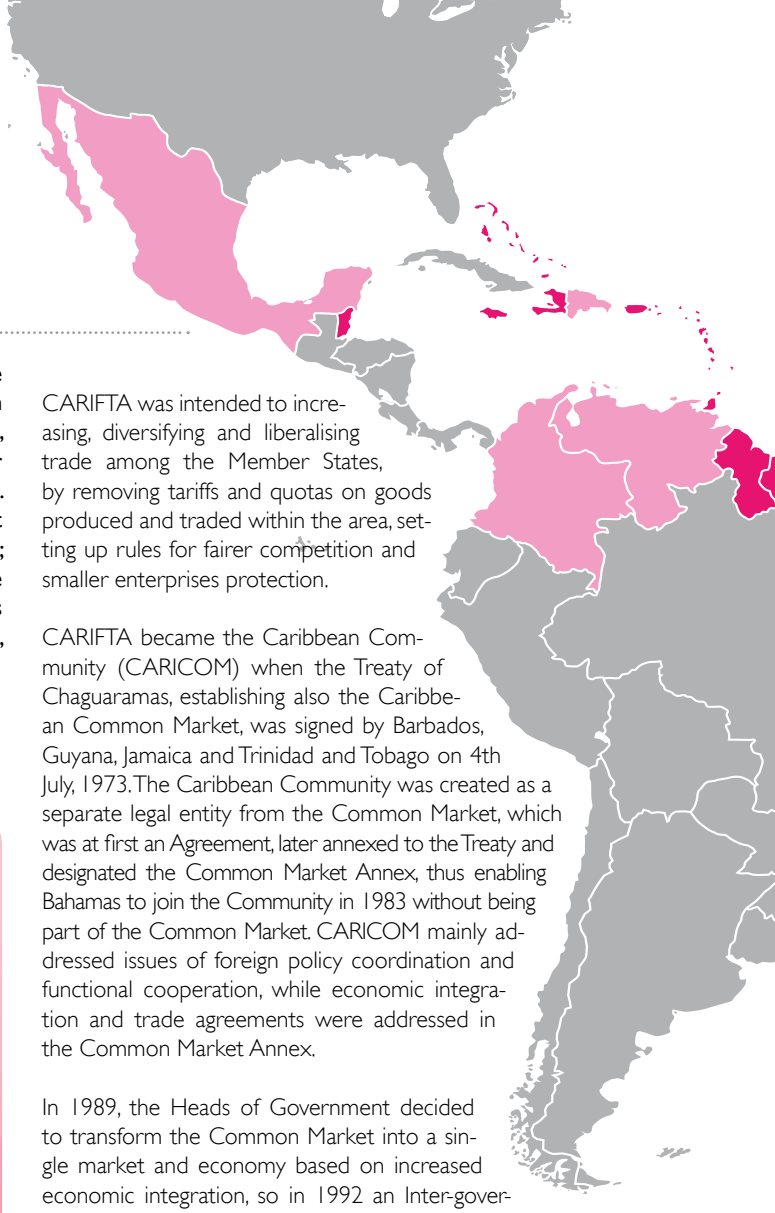
The CARICOM Single Market and Economy



CARICOM consists of 15 full Member States and 5 Associate Member States. It was originally founded as the Caribbean Free Trade Association (CARIFTA) by Antigua and Barbuda, Barbados, Guyana, and Trinidad and Tobago on 15 December 1965, with the signature of the Dickenson Bay Agreement. They were joined on 1 July, 1968 by Dominica, Grenada, St Kitts-Nevis-Anguilla, Saint Lucia and St Vincent and the Grenadines; on 1 August, 1968 by Montserrat and Jamaica, and in 1971 by Belize (former British Honduras). The most recent full membership status was given to Haiti in 2005. Associate Members are: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands.

CARICOM Population

CARICOM Member States	Population
Antigua & Barbuda	86,000
Bahamas	342,000
Barbados	275,000
Belize	307,000
Dominica	73,000
Grenada	104,000
Guyana	762,000
Haiti	10,033,000
Jamaica	2,719,000
Montserrat	5,000
St. Kitts & Nevis	40,000
St. Lucia	172,000
St. Vincent & Grenadines	109,000
Suriname	520,000
Trinidad & Tobago	1,339,000
Anguilla	14,000
Bermuda	68,000
British Virgin Islands	24,000
Cayman Islands	49,000
Turks & Caicos	23,000
Total	17,064,000

Source: CARPHA

CARIFTA was intended to increasing, diversifying and liberalising trade among the Member States, by removing tariffs and quotas on goods produced and traded within the area, setting up rules for fairer competition and smaller enterprises protection.

CARIFTA became the Caribbean Community (CARICOM) when the Treaty of Chaguaramas, establishing also the Caribbean Common Market, was signed by Barbados, Guyana, Jamaica and Trinidad and Tobago on 4th July, 1973. The Caribbean Community was created as a separate legal entity from the Common Market, which was at first an Agreement, later annexed to the Treaty and designated the Common Market Annex, thus enabling Bahamas to join the Community in 1983 without being part of the Common Market. CARICOM mainly addressed issues of foreign policy coordination and functional cooperation, while economic integration and trade agreements were addressed in the Common Market Annex.

In 1989, the Heads of Government decided to transform the Common Market into a single market and economy based on increased economic integration, so in 1992 an Inter-governmental Task Force (IGTF) was established, to work on the revision of the Treaty. By 2000 the IGTF produced nine Protocols, later combined to create the Revised Treaty of Chaguaramas Establishing the Caribbean Community, including the CARICOM Single Market and Economy (CSME), later integrated by protocols on e-commerce, government procurement and trade in goods from free zones. CSME grants to any CARICOM national the right to establish a business in any Member State and be treated as a national of that state. More than 95% of the goods produced in the CARICOM move freely across the Region, and the governments are focusing on removing restrictions on free movement of capital and skilled labour.

On the healthcare side, over the last decades public health in the Caribbean has been coordinated by a series of regional health institutions. In March 2010, the Caribbean Community Heads of Government approved the creation of the new Caribbean Public Health Agency (CARPHA). CARPHA is not yet formally established, but in the Twenty-Second Inter-Sessional Meeting of the Conference of Heads of Government of the Caribbean Community (CARICOM) held in Grand Anse, Grenada, on 25-26 February 2011, Heads of Government urged Member States to sign the Inter-governmental Agreement for a legal establishment of CARPHA. The CARPHA Implementation Plan mapped out the establishment of a fully functional agency on a phased basis between 2010 and 2014. The overall cost for Implementation has been estimated at US$ 55.9 million. The Member State quota contributions are minimum US$4 million per year at least until 2014.

CARICOM Economy

Member State	GNI, million US$	Nominal GDP (basic prices, million US$)	Per Capita GDP, US$	Real GDP growth rate, %
Antigua and Barbuda	958.3	842.3	11,931.4	14.9
Barbados	...	2,632.2	11,646.2	6.56
Belize	...	1051.4	4,158.8	9.1
Dominica	286.1	248.6	4,470.1	4.7
Grenada	498.4	457.1	5,247.6	0.8
Guyana	852.8	751.9	1,179.3	9.1
Jamaica	11,352.9	10353.2	3,872.1	6.1
Montserrat	42.1	39.3	9,026.1	7.6
Saint Kitts and Nevis	461.5	399.9	9,901.4	10.5
Saint Lucia	835.2	747.1	5,484.9	6
St. Vincent and The Grenadines	470.7	405.2	4,759.5	10.7
Suriname	1,801.4	1634.8	3,681.2	16.7
The Bahamas	6751	6660	20,835	4.6
Trinidad and Tobago	17,617.8	18226	14,042.2	20.2

Note: All figures are for year 2006
Source: CARICOM Statistics, CSME Profile 2005-2006

Useful contact:
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Georgetown, Guyana
Tel: +592 222 0001
Email: info@carpha.org
Website: www.carpha.org

Sources:
Caribbean Community (www.caricom.org)
CARICOM Statistics (www.caricomstats.org)
Caribbean Public Health Agency (CARPHA) "Supporting the establishment of the Caribbean Public Health Agency" (www.carpha.org)

U.S. FDA regulations on Medical Devices

Marketing clearance or approval

The Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA) regulates companies that design, manufacture, repackage, relabel or import medical devices sold in the United States, as well as radiation-emitting electronic products, both medical and non-medical.

A medical device must meet the definition contained in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act. Drugs or biological products are not regulated by the CDRH, while electronic radiation emitting products are subject to additional requirements. The FD&C Act also regulates marketing, labeling and market surveillance.

The marketing process of a medical device depends on its classification: FDA can either "clear" a medical device after reviewing a Premarket Notification known as 510(k), or "approve" it after reviewing a premarket approval (PMA) application. Classification of medical devices is based on three risk levels: Class I, Class II and Class III, the highest risk class. Class I devices are considered as low risk devices and are exempt from Premarket Notification, Class II devices require more controls and usually need Premarket Notification, while Class III devices must receive PMA. Some 510(k) submissions and most PMA applications require clinical performance data according to the FDA's Investigational Device Exemption (IDE) regulation, in addition to marketing clearance.

In order to get FDA clearance with 510(k) the medical device must be proven as "substantially equivalent" to another legally marketed device for the same use. Since the approval of the Medical Device User Fee and Modernization Act of 2002, FDA charges a fee for medical device 510(k) reviews, which may be reduced for small businesses, and is independent from FDA's final decision. Class I devices and some Class II devices that have been determined not to require FDA review are considered "510(k) exempt", but they are still subject to general controls on suitability for intended use, packaging and labeling, establishment registration and device listing forms on file with FDA and manufacturing quality system, except for a few class I devices that are subject only to complaint files and general recordkeeping requirements.

Devices requiring 510(k) can be reviewed by an Accredited Person, one of the 12 organizations accredited by FDA to conduct a primary review. FDA must issue a final determination within 30 days after receiving a recommendation from an Accredited Person. Class III devices need Premarket Approval from the FDA, including the submission of clinical data in support of the application. For high risk devices introduced after 1990 manufacturers are required to postmarket surveillance. Postmarket surveillance requirements include the Quality Systems (QS), also known as Good Manufacturing Practices (GMPs) and Medical Device Reporting (MDR) for adverse events.

Besides marketing clearance, basic Premarket Requirements are labeling in accordance with FDA regulation, establishment registration and medical device listing. Both domestic and foreign manufacturers, as well as the initial distributors (importers), must register with the FDA and verify the registered information every year. Manufacturers, contract manufacturers or sterilizers that commercially distribute the device, repackagers and relabelers, specification developers, reprocessors of single-use devices, remanufacturers, manufacturers of accessories and components sold directly to the end user and U.S. manufacturers of "export only" devices must all list their devices through the FDA Unified Registration and Listing System (FURLS).

In Vitro Diagnostic Devices (IVDs) are subject to the Clinical Laboratory Improvement Amendments (CLIA) of 1988, in addition to FDA regulation under the FD&C Act. CLIA established three categories of testing with increasing complexity of the testing methodology: a) waived tests, b) tests of moderate complexity, and c) tests of high complexity. Laboratories in categories b) and c) must meet requirements for proficiency testing, patient test management, quality control, quality assurance, and personnel. Since 2000, CDRH's Office of Device Evaluation/Division of Clinical Laboratory Devices (DCLD) is responsible for the categorization and evaluation of premarket submission of in vitro diagnostic tests. Waived products, devices exempt from premarket notification, and devices under premarket review by other FDA centers are also under DCLD responsibility.

Importing a Medical Device in the U.S.

In order to import medical devices into the U.S., foreign manufacturers must comply with FDA requirements on registration of establishment, listing of devices, quality system manufacturing, medical device reporting of adverse events, and Premarket Notification 510(k) or Premarket Approval, even if the product is authorized for marketing in another country, as FDA does not recognize regulatory approvals from other countries. The foreign manufacturer must also appoint a U.S. agent.
It is important to notice that the initial importer (meaning any importer who markets a device from a foreign manufacturer to the final deliverer or seller of the device to the end user, but does not repackage, or change the container, wrapper, or labeling) must register its establishment with FDA and is subject to both Medical Device Reporting (MDR) and Medical Device Tracking if applicable.

Foreign manufacturers that export electronic products that emit radiation to the United States are subject to the requirements of the FD&C Act, Subchapter C - Electronic Product Radiation Control, including performance standards, labeling, and submission of radiation safety product reports. Importers may submit these reports on behalf of manufacturers. All medical devices that are imported into the U.S. must meet Bureau of Customs and Border Protection (CBP) requirements in addition to FDA. The importer submits entry information to the local

CBP district office, according to what is specified in the letter issued by CDRH. The product code provided to CBP must include a two digit prefix identifying the medical specialty in addition to the three letter code. For electronic products a written declaration on "Declaration of Products Subject to Radiation Control Standards" is required. Most importers ask "filers", domestic customhouse brokers, to fill these forms electronically on their behalf. Filers have access to the Operational and Administrative Systems for Import Support (OASIS), the FDA computerized import system serving as interface between FDA and the CBPs Automated Commercial System (ACS). When an entry is filed with CBP, a copy is also provided to the local FDA district office which determines if the product complies with FDA requirements. FDA may detain a product that appears to be out of compliance with the FD&C Act, and the FDA office will issue a "Notice of FDA Action" specifying the nature of the violation to the owner or consignee, who is then entitled to an informal hearing to submit evidence that the product is in compliance. If he fails submitting such evidence, FDA will issue another "Notice of FDA Action" refusing admission to the product, that has to be exported or destroyed within 90 days, under penalty of an assessment for liquidated damages for up to 3 times its value.

As reported by Zacks Equity Research, FDA is considering how to change the 510(k) device approval protocols. In January 2011 the FDA issued 25 proposals to be implemented during the year to improve the regulatory approval process for medical devices. Among the proposals, the creation of a subset of moderately risky devices ("Class IIb") that would require submission of more clinical data and manufacturing information compared to the existing Class II devices and the reform of the review process for lower-risk devices, clarifying when clinical data are required for a 510(k) application. Industry fears the reform might make device approval more complex and burdensome, and weigh on R&D expenses due to the expected rise in the regulatory bar for approvals. The CDRH forwarded seven of the controversial proposals to the Institute of Medicine for independent review with feedback expected in mid 2011.

Sources:

U.S. Food and Drug Administration (www.fda.gov)
All American Small Business Exporters Association, "How to Import Medical Devices into the U.S." (www.aasbea.com)
Zacks Equity Research, "510 (k) Reform: FDA's Blueprint" (www.zacks.com)

How to access the Brazilian Medical Market

Overview

When it comes to the health and medical industry, Brazil represents an enormous growing market, with a population of 203 million inhabitants (according to the IBGE projection for 2011), which is driven by positive socioeconomic indicators such as growing disposable income. Dilma Rouseff became president this past January in part by campaigning on a political platform of improving healthcare for the citizens of Brazil.

With her election, the medical industry is poised for major growth and investment. Despite this potential opportunity, it is not easy to introduce new companies or products in Brazil. In fact, it is one of the most complex, impenetrable and time consuming market to navigate, one requiring considerable investment resources. According to Brazilian legislation, the production, manufacturing, importing, exporting and sales of any medical, pharmaceuticals and cosmetics products can only be handled by local (Brazilian) authorized companies, registered with ANVISA the National Sanitary Vigilance Agency, an agency of the Brazilian Ministry of Health. Companies must go through a lengthy registration process with ANVISA in addition to obtaining licenses to sell their products within that country. The length of time between filing an application for registration and final approval by the government is variable, but this process takes at least 10 months to complete. Most of manufacturers will also have to comply with specific certificates or accreditations such as Good Manufacturing Practices (GMP), or/and In Metro. While the Brazilian legislation is based on international standards, ANVISA relies on its own set of standards, which may slow the registration process along with complicated relationships with local distributors.

What you need to know about regulations, restrictions and registrations

Depending on the nature of your product, you will need an official notification or a registration from ANVISA. This is the Brazilian counterpart of the U.S. FDA (Food and Drug Administration); Anvisa is intended to promote public health by inspecting and means of health surveillance and also by supervising the sale of products and the rendering of services in the realm of health surveillance; Any and all products related to health, cosmetics and food having a medical application have to be registered with ANVISA.

- **Regulation:** Law No 6360 of 1976, Decree 74.094/97 regulates medical devices in Brazil. Passed in 2001, RDC-185 is the main resolution pertaining to medical devices. It outlines the specific documents necessary in order to register medical devices and equipment with ANVISA. All medical devices not submitted to notification are classified into 4 classes: I, II, III, IV, based upon their risk to the patient. Class I represent the lowest amount of risk and class IV pose the highest. The classification rules are quite similar to those of the FDA and the European Union's medical Device Directive (MDD)

Resolution No 56 from RDC/Anvisa passed in April of 2001 stipulates that all medical devices must meet these essential principles.

Companies that must register their products also must comply with the Brazilian Good Manufacturing Practice (GMP) system of quality requirements. These requirements are specified in Brazilian resolution RDC 59/2000. In 2009, Brazil's regulatory agency (ANVISA) issued a resolution RDC 25/2009 that makes Brazilian GMP certification mandatory for many equipment and device manufacturers starting May 22, 2010. ANVISA now conducts rigorous inspections of domestic and foreign medical device manufacturers to determine compliance with Brazil GMP regulations. Upon successful completion of an audit, ANVISA will then issue the GMP certificate. In addition, if your product has any electronic components you might also need to get an INMETRO certification. And bear in mind, you can also be submitted to clinical tests. Upon completing this lengthy and bureaucratic process, you will end up with a complex and often confusing report issued by the appropriate official agency. To be useful this report requires high proficiency and technical usage of the Portuguese language. All this can lead to high frustration and major headache.

You really only have 3 options

In reality, your choices are limited to the following:

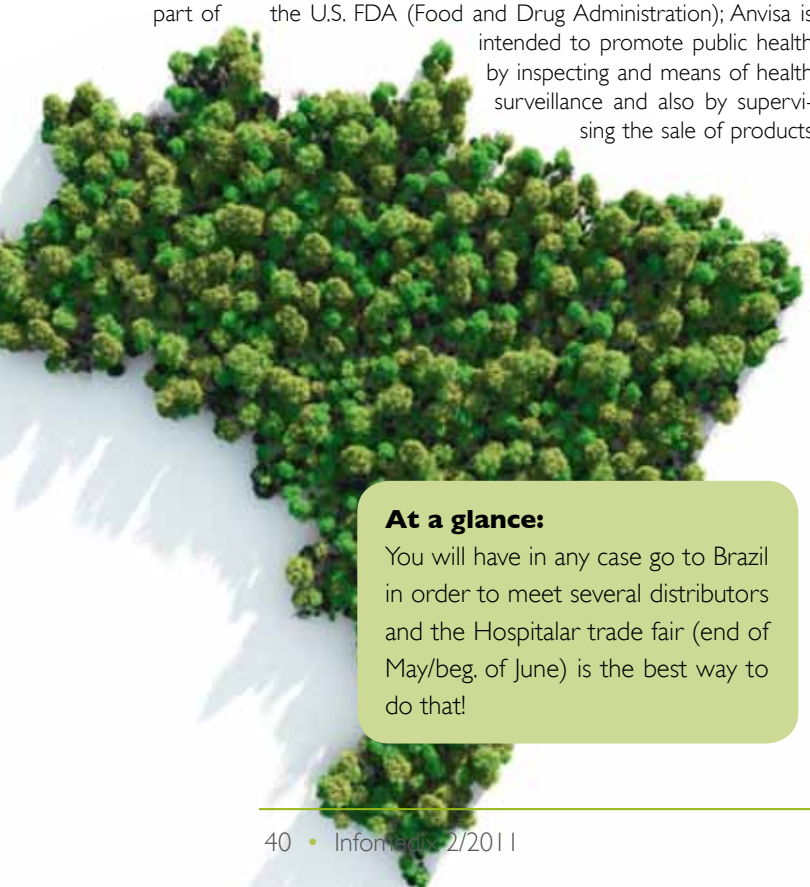
- Create your own Brazilian subsidiary
- Find and negotiate with a local distributor
- Have a trusted third party (master distributor)

1- Create your own local branch: this approach involves the creation, registration of your subsidiary and products in order to bring your product to Brazil. This option is usually slow and costly (medical staff hiring, etc.) and best justified for proven market and businesses with high investment capacity and international infrastructure.

2- Using a local distributor: you will need to find and negotiate with a local distributor knowing that it usually carries several competing brands and often focus on one region or state. Statistically, this option most of the time, results in failure within 24 months and becomes very costly.

3- Joining forces with a trusted third party recognized by ANVISA (master distributor), will be more cost effective and time-saving. Usually companies, such as Mandala Brasil, will offer the following services:

- Determination of the product category (single, family, or system)



At a glance:

You will have in any case go to Brazil in order to meet several distributors and the Hospitalar trade fair (end of May/beg. of June) is the best way to do that!

ANVISA BRAZIL

A **SECURE** AND **CONTROLLED** REGULATORY AND BUSINESS ENVIRONMENT FOR YOUR OPERATIONS IN BRAZIL

- → **Registering and managing your products** in Brazil and / or in Latin America (Master Distributor),
- → **Setting up and registering your company** and its products under Brazilian law,
- → **Identifying distributors** in Brazil and **monitoring** their performance.

- → Rely on the Latin America specialists to register your products with the National Health Surveillance Agency in Brazil (**ANVISA**)
- → **Ensure you get better, faster and more certain results without the usual legal and administrative difficulties.**

WHAT WE DO

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	Cost	Implementation	Risk Level
Creating a local subsidiary	**High** - Property investment(s) - employing a doctor and/or pharmacist - Business trips	**12 to 18 months** - Creating a business structure - Registering your affiliate - Registering your products	**Moderate** - Legal risks - Salary and wage risks - Commercial failure risks - Autnomy and independence
Outsourcing to one of your local distributors.	**Moderate** - Negotiating and ratifying a contract - Often with a reference product and high commission - Annual negotiation - Registration taxes can be paid by the local company	**10 to 12 months** - Language and translation barriers in carrying out your requests. - Lack of responsiveness and transparency from the distributor - Difficulties to train the distributor to your products	**High** - Legal risks (Brazilian contract law). - Commercial risks (competing products) - Risks associated with the ownership of your registration. (exclusive rights) - Obligation to rely on Distributor
Working with a trusted third party specialized in Brazilian regulations (master distributor)	**Low** Presentation of a clear and accurate estimate - Fixed amount per product (with discounts for multiple products)	**8 to 10 months** - Expedited process based on access and established relationship with ANVISA - Your own dedicated bilingual contact - Documentation and case management should be included - Transparency and full autonomy.	**Low** - No salary, administrative or overhead costs. - Operated by a solid and trusted third party who can provide local assistance whenever you need it - No exclusivity agreements. - Choice of commercial partners (local distributors) and control of sales volume

- Definition of regulatory prerequisites (registration or notification)
- Evaluation of classification within the definition of ANVISA
- Identification of other required certifications such as INMETRO
- Pre- audit for Certificate of Good Manufacturing Practice for registration request
- Relay for any commercial, regulatory and administrative operations (product tracking, regulation changes, import letters…)

A step by step registration guide of health products in Brazil

1. Conduct a market study and survey the legal and economic framework of the business climate you wish to enter.
2. Identify product classification based on the risk level, with respect to the National Surveillance Agency (ANVISA).
3. Assign a company (see options table), authorized by Anvisa, to import medical products to Brazil. This company will hold the Anvisa registration for 5 years. Check and conduct a preliminary audit for specific certification and registration requirements.

a) Some electrical devices will have to be certified by research institutes recognized by INMETRO (additional fee).

b) Products classified as high risk, as well as new products of innovating technology must present clinical tests.

c) Product registration of any risk class (Class I, II, III and IV) requires the Good Manufacturing Practice Certificate, as directed in Resolution 59/00 and on Resolution 25/2009 (additional substantial cost).

4. You now can begin the registration process! Application filings to the different services of ANVISA require rigorous monitoring. Along with the registration request, a report must be presented, comprising information related to the product (specific technical language and terminology will be used). Economic data may also be required.

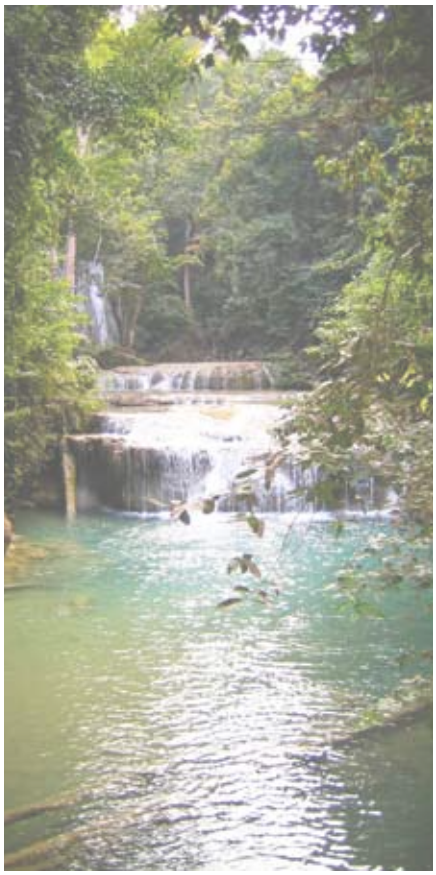
5. Documents will be analyzed by an Anvisa staff. If the registration is approved, the registration number will be published in the Official Paper (DOU). The registration is valid for five years. Note: it is essential to check the request and the publication consistency.

6. Products will be allowed to enter Brazil following the publication of the registration by Anvisa.

Mind you, any mistakes or misunderstandings during this arduous process can cost a significant amount of additional time and money but the importance of the market justifies your efforts and perseverance

Agência Nacional de Vigilância Sanitária

Source:
MANDALA Brasil respresented by CroftHawk France



An Overview of the Quality System Requirements for the Sale of Medical Devices in Canada

Health Canada, under the authority of the Food and Drugs Act, regulates the sale of medical devices and drugs in Canada. On July 1, 1998, new Medical Devices Regulations ("the Regulations") came into force, replacing Regulations which had been in effect since 1975. These regulations are amended from time to time to reflect new policies or minor housekeeping changes. A consolidated version can be viewed on the following website:
http://laws.justice.gc.ca

The current Regulations are based on a risk assessment and risk management approach with a balance of pre-market review, quality systems and post-market surveillance.

One system classifies in vitro diagnostic devices. The second classifies all other medical devices and addresses the majority of devices available to Canadians. Both systems classify devices into one of four risk classes, Class I representing the lowest risk and Class IV the highest.

The system for non-in vitro medical devices utilizes criteria such as invasiveness; length of invasiveness; body system exposed to the device; whether or not the device relies on a source of energy; whether the device diagnoses or is therapeutic; and whether or not the device delivers energy to the patient, in assigning a level of risk to a device. Special rules are included to classify, for example, devices incorporating animal tissues or devices that use recombinant DNA technology in their manufacture.

A set of safety and effectiveness requirements form the basis of the Regulations. These have been modeled on the "essential requirements" of the European Directives. For the majority of devices, demonstration of compliance with these requirements to Health Canada is assessed through a pre-market device licensing requirement; however, all devices are required to meet these safety and effectiveness requirements, as appropriate.

Before a Class II, III or IV medical device can be imported, sold or advertised for sale, a device licence must be obtained from Health Canada. Class I devices are exempt from device licensing requirements. Although manufacturers are responsible for classifying their devices, classification is subject to verification by Health Canada. The amount of information required to be submitted to obtain a device licence increases the higher the risk class of the device.

To monitor medical device distribution from the time of manufacture to use, importers and distributors are required to obtain an establishment licence. Manufacturers of Class I medical devices distributing directly to users are also required to obtain an establishment licence. Issuance of an establishment licence is contingent upon attestations from the applicant that recall, mandatory problem reporting and complaint handling procedures are in place, and that proper distribution records are maintained.

Source:
Industry Canada-
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Haiti, one year later

Before the 7.0 magnitude earthquake struck Haiti on 12 January, 2010, 67% of the population was living on less than US$ 2 a day, 25% of children were malnourished, and an estimated 40% of the population had no access to basic health services, resulting in poor geographical coverage and major inequalities in healthcare delivery.

Haiti also had the highest rates of child mortality in the Americas, the highest rate of tuberculosis in the Western Hemisphere, and HIVV/AIDS prevalence was at a 2.2% infection rate. About 220,000 people died in the earthquake, over 300,000 were injured and nearly 1.5 million lost their homes. Moreover, a cholera outbreak started in October 2010 and Hurricane Thomas hit the country in November, exacerbating an already critical situation. A year later, one million people remain in temporary settlement sites throughout Port-au-Prince and other affected areas. Eight hospitals were totally destroyed, and 22 seriously damaged in the three departments most affected by the earthquake (West, Nippes, South-East). Haiti suffers chronic shortage of basic medical and surgical supplies, and biomedical equipment and also lacks professionally trained technicians and engineers to repair and maintain diagnostic and treatment equipment.

Immediately after the earthquake, PAHO/WHO started helping the MSPP coordinate the work of international and national agencies and NGOs that have brought in health personnel and equipment to provide primary health care services in the affected areas. Interventions accomplished included the establishment of 17 field hospitals in the most devastated areas to provide emergency medical care, distribution of 345,000 boxes of emergency medical supplies between January and March through PROMESS, the medical warehouse managed by PAHO/WHO, implementation of the post-disaster vaccination program delivering over 900,000 vaccine doses to the most vulnerable children and adults, mapping of all health facilities in Haiti, coordination of the response to the cholera outbreak and provision of essential medicines and medical equipment for the treatment of cholera patients.

Basic medical services are currently provided through field hospitals, mobile health clinics, and the creation of referral networks to functioning hospitals. Free of Charge Obstetric Care (SOG) for pregnant women and newborns expanded the content of the health package after February 2010, involving 63 health institutions across the country. Moreover, the SIG (Soins Infantiles Gratuits) was implemented after the earthquake, providing free care for children under five thanks to an agreement with public and private hospitals similar to that of the SOG. The 27 largest hospitals in the country are currently providing services under the SIG, which treated more than 15,000 children beyond the base line numbers so far.

PAHO/WHO, in cooperation with the International Atomic Energy Agency (IAEA), also provided basic radiology services to hospitals inside and outside Port-au-Prince, including 8 mobile X-ray machines and 4 automatic film developers and related supplies, which have been delivered to strategic health facilities designated by the MSPP. PROMESS supplied X-ray films, developer liquids, lead aprons, protective panels, and personal dosimeters for these machines, and training is ongoing for personnel on proper use of the portable machines, radiation protection, storage of films and chemicals, darkroom techniques, machine maintenance, patient positioning, and use of different film screens and speeds.

A major issue remains the need to ease access to health care for displaced Haitians, still about a million people. International agencies such as Cuban Medical Brigade, Partners in Health, Aide Médical International, Merlin, Médecins Sans Frontières, the International Federation of the Red Cross and its National Societies, and Médecins du Monde, among others, provide mobile health services to meet this need.

However, the country's health system is still disorganized, lacking information on services offered by health facilitie and their location, sparsely distributed. MSPP strategy for reconstruction (Plan Intérimaire du Secteur Santé) aims at rebuilding the Haitian health system by ensuring provision and continuity of services in all structures, identifying and rehabilitating affected structures, facilitating financial access to services and supporting vulnerable groups such as pregnant women, children under five, disabled peoples, and people with psychological trauma caused by the earthquake. Nine departmental hospitals have been identified to be strengthened in an effort to decentralize the health care system. Reinforcing public hygiene and sanitation measures and reconstructing damaged hospitals (together with the construction of new ones) are essential tasks, with the provision that all new health facilities and the reconstruction of the existing health structure should include measures to make them resistant to future events. Of the 156 reconstructions projects identified in the healthcare sector, only 56 are to be probably completed by October 2011: 11 of them of a total of 66 are financed but not started yet, 23 of them of a total of 43 are currently being developed and 22 are actually completed, but consist more of consolidation of already in place facilities and implantation of small clinics.

Although the focus of NGOs has recently been on facing cholera, response to the outbreak has improved in the last few months with decreasing mortality ratio and some NGOs begin leaving the country. There will be a greater need for funds and trained personnel to reinforce fixed health facilities, as coverage offered by mobile clinics will be reduced and humanitarian relief will have to be integrated by the building of a sustainable health system. During the Millennium Development Goals summit of 20th – 22nd September in New York, the Haitian government renewed its commitment to provide free maternal, neonatal and infant healthcare by 2015. Long-term needs also require more financing for drinking water distribution and waste management, as the overall water supply and sanitary procedures remain largely insufficient especially in the camps.

Sources:

Pan American Health Organization, "Earthquake in Haiti – One Year Later" (new.paho.org)
Real Medicine Foundation (www.realmedicinefoundation.org)
Doctors of the World (www.mdm-international.org)
Interim Haiti Recovery Commission (www.cirh.ht)

How to achieve universal coverage?

The WHO report "Health systems financing: the path to universal coverage" presented on 22nd November, 2010 to a ministerial conference on health financing in Germany, maps out the strategies to modify health financing systems to guarantee universal coverage and improve health outcomes, particularly in low income countries. Trends such as population ageing, increasing burden of non-communicable and chronic diseases, and the progress of technology making newer but more expensive treatments available, are all factors influencing rising healthcare costs.

According to the report, global annual expenditure on health is currently about US$5.3 trillion. Although representing only 18% of the global population, OECD countries account for 86% of this spending, with a minimum per capita expenditure that is usually over US$2,900. But some lower income countries managed to improve their healthcare coverage even without this level of health expenditure, often by lessening the dependence on out-of-pocket payments and shifting to prepayment structures organized though general taxation and/or compulsory contributions to health insurance. The WHO estimates that most of the world's 1.3 billion poor have no access to health services because they cannot afford to pay for them. Moreover, many people having to pay for treatment at the point of delivery suffer financial catastrophes, defined as paying more than 40% of household income directly on basic healthcare needs. In some countries up to 5% of people are driven below the poverty line for this reason, about 100 million people a year.

The ultimate goal of health financing systems is to provide all people with access to needed health services (including prevention, promotion, treatment and rehabilitation) of sufficient quality to be effective and prevent people to be exposed to financial hardship by using these services. The outcome depends on three factors: who is covered from pooled funds; what services are covered; and how much of the cost is covered. On this basis, policy-makers must decide how to raise and manage funds.

In order to make sufficient funding available, the basic requirement is to set prepayment structures able to cover costs when people get ill, including coverage for those who are unable to contribute financing the system. On the other hand, such structures are often underdeveloped or inefficient in lower income countries, needing support by international donors, but efforts should focus more on helping these countries develop their own health financing system in view of universal coverage, rather than just funding projects or programmes through separate channels. On the other hand, recent healthcare reforms in China and USA aiming at expanding coverage to neglected groups of the population show that this is not merely an issue for low or middle income countries. Although at different stages in the process, all countries need to address the problem of rising healthcare costs and their burden on the national income, keeping an eye on two important indicators: the incidence of financial hardship associated with direct payments and the extent to which people are able to use needed services. Strategies may then vary according to the different health systems profiles, sometimes focusing more on extending coverage in quantity even if the list of services is small, sometimes targeting specific uncovered groups to make quality care easily available to them. The approach adopted by many countries in the path towards an expanded social security system, to begin with employees in the so-called formal sector, involves the risk to create a two-tier systems and to further disadvantage those left uncovered.

The WHO highlights three practical ways to move towards increased health coverage: raise more funds for health; provide an adequate level of financial risk protection so that people who need services are neither deterred nor subject to impoverishment from seeking them; improve efficiency and equity in the way funds are used.

In order to raise additional funds it is crucial that governments make health a higher priority in their budget and find new or diversified sources of domestic funding. The report points out to Rwanda as a supporting evidence that all countries can potentially extend financial risk protection and equitable access to health services. Per capita national income in Rwanda is about US$400, with a set of basic services covered through a system of health insurances costing US$37 per capita. Rwanda benefits from the financial support of international donors, but the government also spends 19.5% of its annual budget on health. Although 182 WHO Member States have comparable or superior levels of per capita GDP to Rwanda's, many are still far away from universal health coverage. WHO estimates that if the governments of the world's 49 poorest countries allocated 15% of state expenditure to health, they would almost double the current available funding by adding US$15 billion per year. Efficient tax collection systems, tobacco or alcohol taxes and currency transactions levies are some of the ways to increase tax revenues to be used for healthcare, according to the different economic situation and trade composition of each country. It is also important to underline that if all higher income countries kept the promise to allocate 0.7% of their GDP to official development assistance, three million lives could be saved in lower income countries by 2015.

Proper use of health funding is crucial to improve access to care for the entire population, but it requires removal of financial barriers to obtaining care. Reducing the dependence on direct, out-of-pocket payment is an important step towards this goal, which yet implies finding resources elsewhere to replace the fees charged for services. Faced to the financial risk of paying for health services, many households simply defer or give up seeking treatment. The best way to address inequalities in poorer groups' ability to access treatment is therefore to pool funds in order to share the risk among a great number of people. Small voluntary health insurance such as local sickness funds or community health insurances may cover primary-level care costs and part of the cost of hospitalization and constitute a stepping stone to bigger regional schemes, gradually consolidated into national risk pools if properly supported by the government. This process was in place in many countries who are now closer to universal coverage, such as Germany and Japan.

Most health financing systems are based on hybrid models collecting resources from a mix of public and private sources, which do not necessarily need to determine how funds are pooled or who benefits. For instance, insurance contributions from employers and/or employees can be pooled together with contributions from general government revenues. Moreover, investment in adequate prevention, primary-level care and rural health services is the basis to overcome additional, non-financial barriers such as transportation difficulties or costs and social or cultural issues such as gender discrimination.

Last but not least, improving efficiency in health spending may release resources to expand coverage and provide better care at minor costs. Medicines are a main field of intervention, as they account for 20–30% of global health spending, slightly more in low- and middle-income countries. France, for instance, has adopted as a strategy to use generic drugs instead of brand names where possible, saving about US$2 billion in 2008. Countries can improve efficiency by deciding which services to purchase based on information on the health needs of the population and link payments to providers on their performance and to information on service costs, quality and impact, and by reducing hospital inefficiency often related to excessive inpatient admissions and length of stay, for instance by expanding prevention programs and supporting the development of home care and outpatient care services.

On general terms, while health finance reforms occur in many countries at different levels of economic development, there is evidence to support WHO's claim that programmes that come closest to meeting the needs of their populations should include some form of prepayment and pooling to ensure stable and sufficient funds for health, but also that national wealth is not a prerequisite for moving closer to universal coverage.

Source:
World Health Organization (www.who.int)

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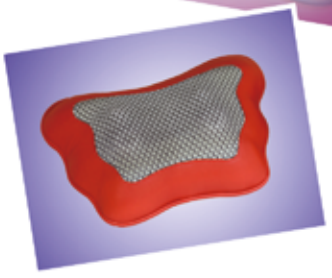

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Health Data and the Delivery of Sustainable Healthcare

Health professionals and policy-makers rely on the right data being available to make decisions about patient treatment and delivery of services; the better the quality of the data, the better decisions they can make. This access to quality data is more critical than ever given the challenge that global health systems now face to deliver high-quality and accessible care under increasing fiscal pressures. Over the past 30 years, healthcare costs have risen at a steady rate and, in the absence of successful health system reform, are expected to continue to increase disproportionately to other sectors of the economy).

Recognizing the role that effective health data management plays in the quality, accessibility and efficiency of health services can help stakeholders address today's challenges and continue to improve health services – both in terms of quality and affordability. However, across all varieties of health systems, accurate health data are not available when and where they are needed. This lack of data can lead to ineffective or unsafe delivery of services, poor patient choices and wasted resources. Effective management of health data is a prerequisite to achieve individual treatment and population health management goals, along with those for overall health system performance.

Delivering Benefits at All Levels

Improving the use of health data can provide a wide range of benefits across the entire health landscape – patients, providers, administrators, governments, researchers, etc. At one end of the spectrum, data can be used to improve treatment and minimize unwitting harm; at the other end, it can be aggregated and analysed to drive decisions about national or international health policy. Health data can deliver benefits for both emerging and developed countries, including:

Key Health Data Challenges:

1. Availability
2. Accessibility
3. Data quality
4. Standardization
5. Digitization
6. Rights/protection
7. Secondary use
8. Global stewardship

• **Improved health outcomes**. Health data can be used to better inform individuals and caregivers, provide more streamlined healthcare processes and improve timeliness and effectiveness of care. It can also support the advancement of medical knowledge and improve early diagnosis and disease prevention. With increased access to, and analysis of, clinical data, critical information on the success of individual programmes can provide key input into decisions on prioritizing investments and resources – particularly important in the developing world. Unfortunately, the current practice of systematically using data to improve patient outcomes varies significantly by country

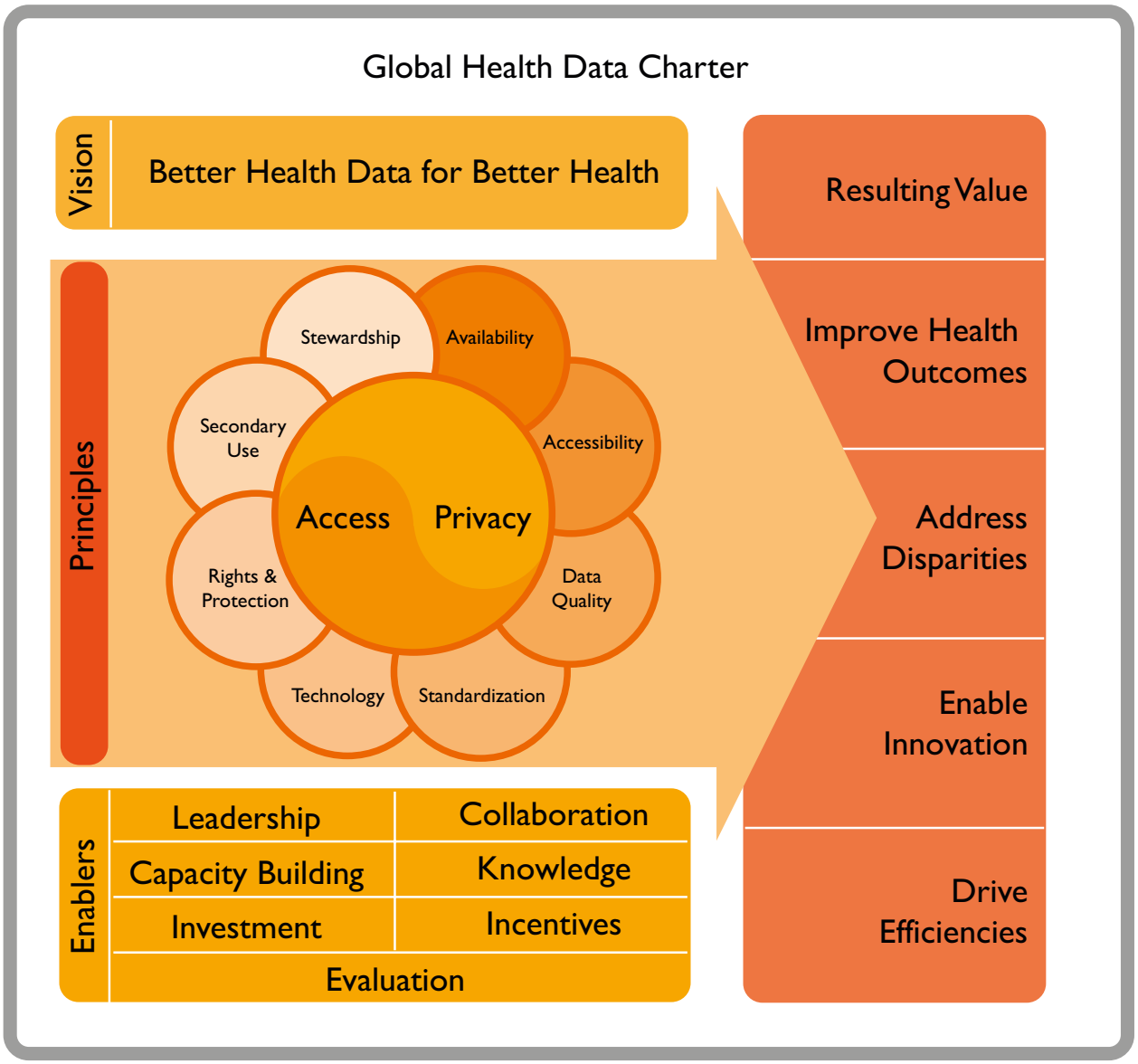
• **Greater innovation.** Health systems around the world are in the process of much-needed transformation. Advancements in technology and improvements in the interoperability of health systems, coupled with efforts to standardize and improve the quality of health data, provide opportunities to use health data in increasingly sophisticated and cost-effective ways. Innovation and improved data management practices will drive ever more powerful applications in disease prediction (biomedical informatics), personal health management systems, telehealth (including mobile health), public health surveillance and biomedical research.

• **Fewer disparities.** Many developing countries do not currently have the infrastructure or resources – money, people and technology – needed to appropriately collect and apply health data. Disadvantaged populations will benefit the most from improved access to health data, advances in information management and innovative technology.

• **More efficient health systems.** Analysis of health data by providers and payers can deliver increased time and cost-efficiency through improved productivity, avoided waste, less duplication of effort and resource optimization. These benefits will go a long way in making health systems affordable and sustainable.

Key Health Data Challenges

Given the benefits of quality health data for decision-making, there is an ever-growing demand for data. Health issues are more complex than ever before, necessitating quicker access to more and better data. Patients and practitioners are demanding just-in-time access to health records to make better decisions about their care. Clinicians are pushing for more evidence-based decision-making. Organizational leaders are requiring more administrative and resource data to improve efficiency. Governments are requesting more reporting as part of a push for greater accountability. In addition, there are more health-related researchers



and analysts who need data to conduct important studies that will benefit individuals and populations. It is nevertheless important to recognize that without proper attention to the design, implementation, security and management of health data systems, their potential benefits will not be realized and resources will be wasted.

In summary, there are a number of key challenges that need to be addressed, including:

1. Availability: There are many sources of valuable health data that are deemed to be proprietary and are not made available when and where they are most needed.

2. Accessibility: Often individuals and users of health data do not know what data exists. In addition, there does not appear to be any comprehensive global inventories of health data sources at this time that would assist users in knowing where the data can be accessed.

3. Data quality: There are many situations in which high-quality health data are not available to support informed decision-making and analysis. Some reasons for poor data quality include:

a. Terminology variations – differences in how data are described when they are collected is a key problem – inconsistent definition of terms is a key contributor to data quality problems.
b. Entry errors – databases in many cases contain entry errors, multiple common entries and other redundancies that inevitably have led to incorrect or incomplete data.
c. Inconsistency – changing reporting standards over time leads to the incompatibility of data.
d. Timeliness – most data which have been collected manually are out of date to some degree by the time they are published and made available.

4. Standardization: The standardization needed to share health data is difficult because of the complexity and fragmentation of the healthcare sector. Not only is there a lack of implementation of harmonized standards, taxonomies and terminologies that could help codify data, but also the number and range of technical systems present real challenges in terms of interoperability – a critical driver of success when sharing health data.

5. Digitization: The move from paper health records to electronic health records (EHRs) has been widely recognized as an important prerequisite to transform healthcare, thus making our health systems more sustainable. However, the adoption of EHRs has lagged. Even though some developed countries have made significant investments to promote the use of EHRs, physician uptake has been slow.

6. Rights/protection: The public has expressed concern over unauthorized access to personal information, in particular health data. Although legislation and standards are being developed around the world to deal with the privacy and security of personal health data, countries still lack comprehensive policies. In addition, there have been few attempts to harmonize data protection standards.

7. Secondary use: There is a lack of clarity on the appropriate practices for the sharing and use of health data for purposes other than the delivery of individual health services (e.g. for public health, research and commercial uses).

8. Global stewardship: An accountability mechanism is needed to ensure an individual's rights to health data privacy, along with practices to promote optimal health data management. Although some progress has been made at the national level, efforts to develop global data stewardship principles do not exist.

Despite these challenges, the value of developing a charter is clear. Improving health data management and providing better access to health data can offer profound benefits to both recipients and providers of health services around the world.

The development of a Global Health Data Charter provides a crucial mechanism to engage the broad range of global stakeholders necessary to take the first step towards realizing the vision for better health.

A Global Charter for Health Data

The World Economic Forum, supported by Deloitte and a broad group of stakeholders, developed and launched a Global Charter for Health Data (the Charter) in early January 2011. The Charter outlines the key principles, values and vision for aggregating and using health data and for responding to challenges related to the collection, analysis and application of high-quality health data. It was developed to encourage better data management practices that will in turn improve the decision-making processes, resulting in individuals, communities and health providers making informed decisions and ultimately leading to better health.

This year will be devoted to enhancing the Charter's visibility though Forum events and external conferences, to generate interest from both the business and non-business community in endorsing the Charter's values and principles.

The Charter has received endorsements from a wide variety of international organizations, NGO's and private sector companies.

To download the full Charter, please follow this link:
http:// www3.weforum.org/docs/WEF_HE_GlobalHealthData_Charter_2011.pdf
To see a list of the Charter's endorsers, please follow this link: http://www3.weforum.org/docs/WEF_HE_GlobalHealthData_Charter_2011.pdf

Should your organization be interested in endorsing the Charter, please contact datacharter@weforum.org.

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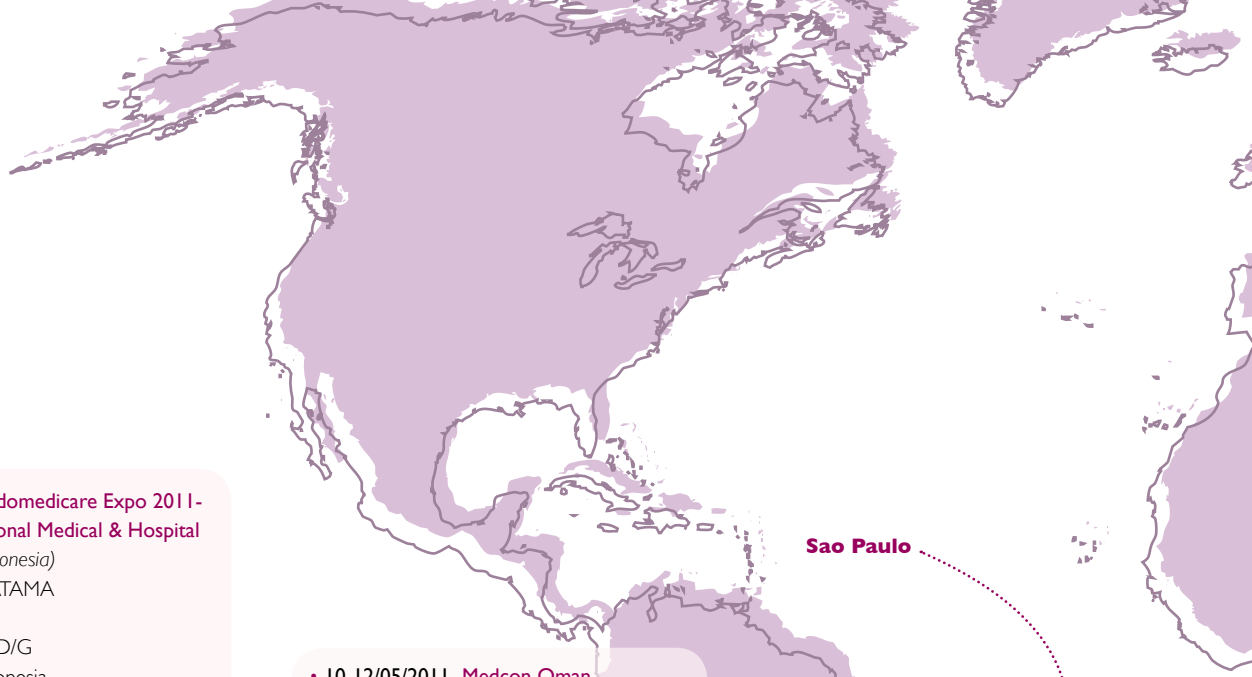

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Fax: +62 21 634 0140 // 634 2113
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Website: www.kristamedia.com // www.indomedicaexpo.com
Venue: Assembly Hall, JCC Senayan, Jakarta

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Venue: Johannesburg Expo Centre, Nasrec

• **10-12/05/2011** Hospital Build Asia 2011
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IIR Asia Pacific
205 Henderson Road
#03-01 Henderson Industrial Road
Singapore 159 549
Contact person: Ariel Tan
Tel: +65 6517 6893
Email: ariel.tan@iirx.com.sg // hospitalbuildasia@iirx.com.sg
Website: www.hospitalbuildasia.com
Venue: Marina Bay Sands, Singapore

• **10-12/05/2011** Medcon Oman
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Al Nimr International Exhibition Organizers
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Office location: O.C. Centre, Ruwi, 8th floor, office #802
Sultanate of Oman
Tel: +968 24 700 656
Fax: +968 24 799 737
Contact person: Ms. Ulrika Varela, Project Manager
E-mail: ulrika@alnimrexpo.com
Website: www.alnimrexpo.com/medcon.html
Venue: Oman International Exhibition Centre

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ITE Group, Plc. / GiMA GmbH
Project Manager: Cornelia Limbach
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Fax: +49 40 23524410
E-mail: limbach@gima.de
Website: www.kihe.kz
Venue: Atakent Exhibition Center, Almaty

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Vietnam Medi-Pharm 2011
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Vietnam Advertisement & Fair
Exhibition J.S. Company - Vietnam
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Fax: +84 49365568
Email: Vietfair@vnn.vn
Website: www.vietfair.vn
Venue: Vietxo Friendship Cultural Palace

16-17/05/2011
EuroMedtech 2011
(Turin – Italy)
European Contact Person: Claire Macht, EBD Group
+49 89 2388 7560
cmacht@ebdgroup.com
USA Contact Person: Maia Rene, EBD Group
+1 760 930 0500
mrene@ebdgroup.com
Venue: Torino Incontra Conference Centre - Turin, Italy

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Website: www.pgpromotion.fr // www.health-it.fr
Exhibitors Relation: Kheira Benammour
Tel: +33 1 73281596
E-mail: kheira.benammour@fr.cmpmedica.com
Venue: Paris Expo - Porte de Versailles, Pavillon 1

17-20/05/2011 Bulmedica - Buldental 2011, 46th International Specialized Exhibition
(Sofia – Bulgaria)
BULMEDICA
Project Manager: Maria Jeliazkova
Tel: +359 2 9655 277
Fax: +359 2 9655 231
E-mail: mjeliazkova@iec.bg
Website: www.iec.bg // www.bulmedica.bg
Venue: Inter Expo Center

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Tel: +7 383 2106290 // 2208330 ext. 336
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Fax: +55 11 3897 6191
E-mail: international@hospitalar.com.br
Website Odontobrasil: www.odontobrasil.net
Website Hospitalar: www.hospitalar.com
Venue: Expo Centre Norte, Sao Paulo, Brazil

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• 11-14/06/2011 14th IranMed 2011
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Mobile: +963 94 213131
E-mail: united.exh@mail.sy // info@syrianmedicare.com
Website: www.syrianmedicare.com
Venue: Fairground, Airport Road

• 23-26/06/2011
Taiwan Health 2011
(Taipei – Taiwan)
Taiwan External Trade Development Council (TAITRA)
Contact person: Ms. Su Lu
Exhibition Section 4, Exhibition Dept., TAITRA
P.O. Box 109-865
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Website: www.taihealth.com
Venue: Taipei World Trade Center

JULY

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Orbitz Exhibitions Pvt Ltd
101, Navyug Industrial Estate, T. J. Road,
Sewri, Mumbai - 400015 India
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Fax: +91 22 2410 2805
E-mail: rohini@orbit-star.com
Website: www.meditec-clinika.com
Venue: Palace Grounds, Bangalore, India

• 04-06/07/2011 **ACEM Asian Conference for Emergency Medicine 2011**
(Bangkok – Thailand)
Lawson-Marsh Event Co., Ltd.
Bangkok 10900 Thailand
Tel: +66 2 940 2483
Fax: +66 2 940 2484
E-mail: acem2011@lawson-marsh.com
Website: ACEM2011.org
Venue: Centara Grand & Bangkok Convention Center at CentralWorld

AUGUST

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(Miami Beach-Florida – USA)
FIME International Medical Exposition, Inc.
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Sarasota, FL 34235 USA
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Fax: +1 941 366 9861
Venue: Miami Beach Convention Center
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SEPTEMBER

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Fax: +49 40 23524410
E-mail: limbach@gima.de
Website: www.bihe.az

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(Bangkok, Thailand)
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E-mail: shirley@mda.com.sg
Michelle Leong, Project Manager
E-mail: michelle@mda.com.sg
Venue: Queen Sirikit National Convention Center
Bangkok, Thailand

• 15-17/09/2011 **Baltmedica 2011**
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Tel: +370 5 268 6824
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E-mail: medica@litexpo.lt
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INFOMEDIX INTERNATIONAL

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= ISO 9001:2010 =

• *Managing Director:* Baldo Pipitone
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Publishing House/Editore: Infodent Srl
Printer/Stampa: Graffietti Stampati Snc -
S.S. Umbro Casentinese Km. 4,500
01027 Montefiascone (VT) ITALY

n° 2/2011 - aut. trib. VT n° 528 del 21/07/2004
Quadrimestrale di informazione tecnico scientifica

Poste Italiane s.p.a. - Sped in AP - D.L. 353/2003 (conv. In L. 26/02/2004 n°46) art. 1 comma 1 DCB VITERBO
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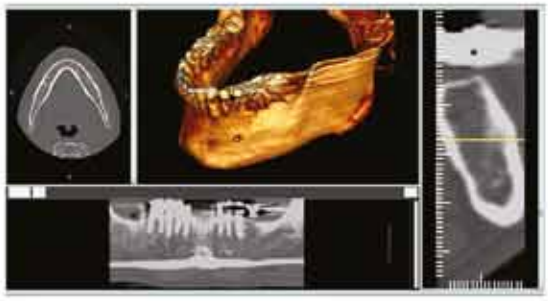

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