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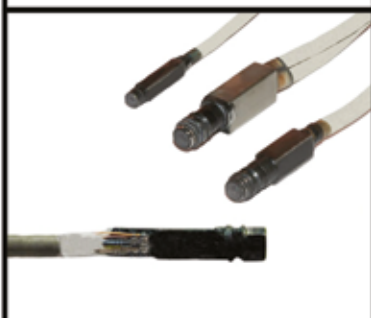
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Multilingual Formação de Reparação e de Consultoria



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"1,250 companies in the healthcare industry meet in São Paulo / Brazil to introduce new products and technologies for hospitals..."

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Mimosa S.r.l. - Sanyleg

Via Lombardia 21

46041 Asola (MN)- Italy

Tel: +39 0376 729582- Fax: +39 0376 729584

E-mail: info@sanyleg.com - Website: www.sanyleg.com

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The basis of Ekom s.r.o. production is formed by oil-less dental compressors, dental suction units and relevant accessories for application in dental surgeries, laboratories and central compressed air systems, along with medical compressors for supplying lung ventilation equipment with medical compressed air. Recently, in the field of medical compressors, EKOM has extended the range of well known compressors DK50 D and DK50 DM by new products – DK50 DS and DK50 DE. The compressors belonging to DK 50 DS line differ from the previous ones not only by the new colour and the change in design, but in particular

by new microprocessor-controlled unit. Along with high-end level medical compressors Ekom s.r.o. introduces simplified versions of DK50 DS compressor range under the designation DK50 DE. Obviously the mentioned products meet the quality and safety standard in accordance with the international European directive MDD93/42 EEC, the American k510 (FDA) as well as the Canadian CMDCAS system.

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and completely safe. Thanks to the vacuum technology used, the handpiece lifts the panniculus adipose so that the ultrasonic wave action concentrates solely on the portion of tissue to be treated, thus ensuring safe treatments and excellent results that are visible from the very first application.

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Innovative Endoscopy Components, LLC is providing valuable products and services to Endoscope Distributors and Endoscope Repair Companies in over 40 countries worldwide. Our extensive inventory includes autoclavable, HD compatible Rigid endoscopes as well as Cameras, Light sources, Fiberoptic Light cables etc. all Made in Germany. We are also a supplier of Eberle Shaver systems and shaver blades. New and pre-owned Endoscope

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EXIPER is a system for Chemohyperthermic procedures in local or regional compartments of the human body in patients hit by cancer.

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Highlights

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2012

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A new approach to test HbA1c

Caretium 凯特

Caretium Instruments Co. Ltd located in Shenzhen city (CHINA) has recently released a new version of semi-auto chemistry analyzer (**model NB 201 C**) equipped with filter of 750 nm and micro-cuvette in quartz. With this specific configuration, this analyzer can adapt the testing of HbA1c by enzymatic method, on top of routine chemistry

testing. For further details, please visit www.caretium.com.

www.caretium.com / info@caretium.com Visit us at: 2012 AACC Clinical Lab Expo, South Hall - Booth 3029



REXMED Medical & Laboratory Equipment Turnkey Project Solution



REXMED Industries Co., Ltd. was established in 1976 as a professional manufacturer and exporter of medical and laboratory equipment in Taiwan. At present our products are popularly applied by hundreds of domestic hospitals, health center, medical schools, pharmaceutical industries, biochemical companies, dental clinics and scientific clients, and also export to more than 150 countries around the world. Please refer on our website for our completed turnkey project: <http://www.rexmed.com/news/project>

Medical Equipment: Suction unit, autoclave sterilizer, operating table, ophthalmic table, delivery table, veterinary table, stretcher, hospital bed, operating lamp, ENT treatment unit, treatment chair, slit lamp, dental unit.

Laboratory Equipment: Ultrasonic cleaner, water bath, immersion cooler, shaker, fermentor, incubator, oven, cell culture roller, environmental chamber, cooling cabinet, differential blood cell counter, platelet rotator, platelet shaker, hot plate, vortex mixer, roller mixer, centrifuge.

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... Highlights

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Highlights

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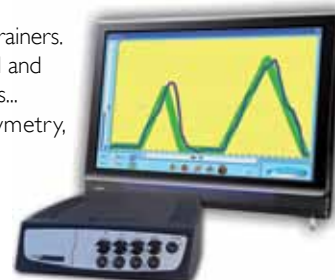
All treatment protocols are designed in partnership with leading international trainers. Applications for therapy: urogynaecology, men urology, proctology, sport, central and peripheral neurology, traumatology, rheumatology, hemiplegia, vascular, aesthetics...

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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.

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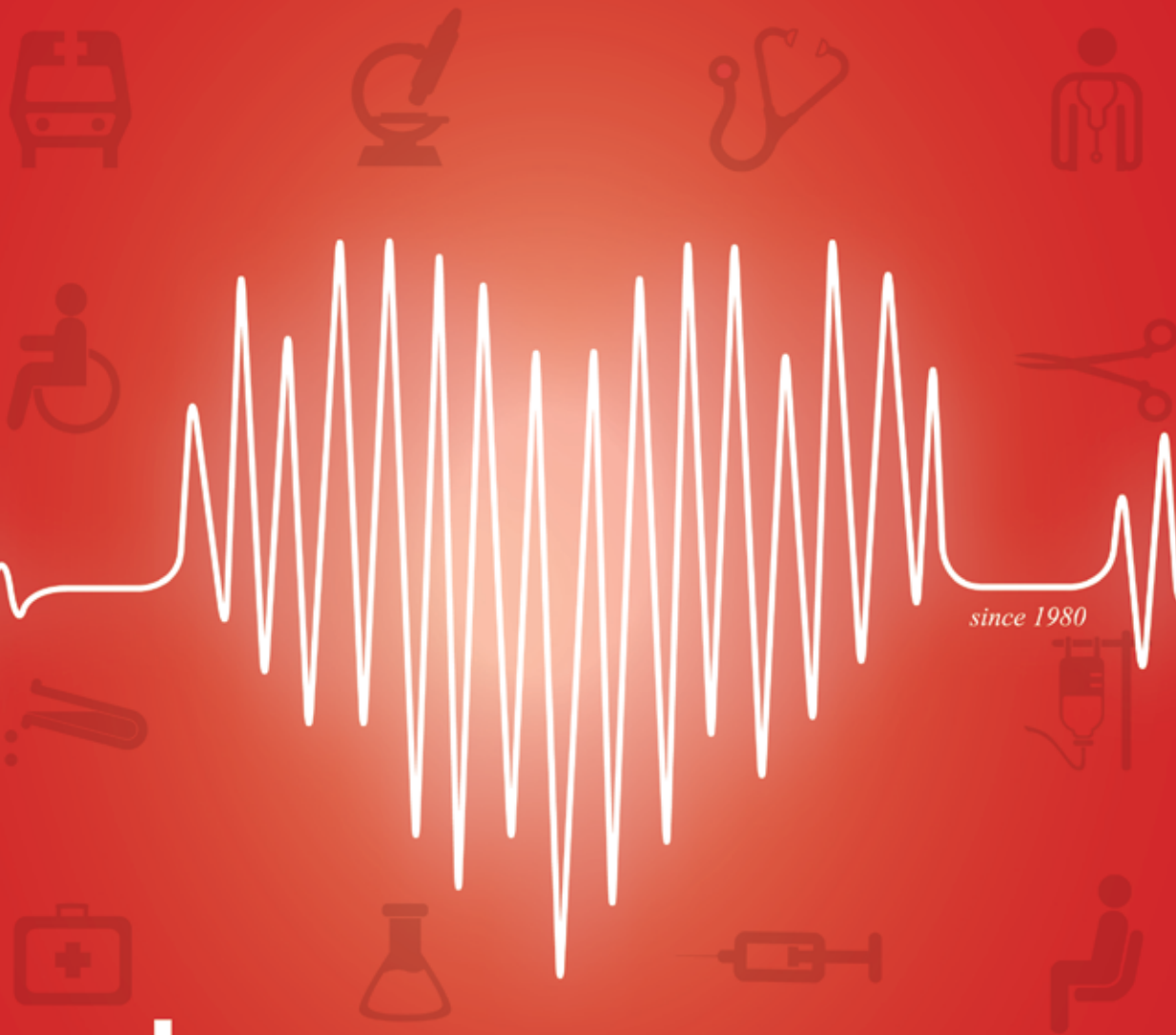
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Operon- Immuno and Molecular Diagnostics



Operon, Inc. is a private company founded in 1973 dedicated to Research, Development, Manufacture and Sale of in vitro diagnostic products with a presence in all continents. The template is up more than 60 people and the average age is 35 years. 30% of staff work in R + D + i. The facilities cover a total of 4000 square meters. The products are distributed in over 40 countries around the world and exports over 85% of turnover.



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- Immunochromatographic rapid tests
- Molecular diagnostic tests

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HEALTHCARE & MEDICAL EVENTS CALENDAR 2012

www.healthcare-events.com



Analitika Expo
10th International Exhibition for Scientific and Laboratory
Equipment, Technologies & Innovations
10 - 13 April 2012 • Moscow, Russia



AstanaZdorovie
International Kazakhstan Exhibition on Healthcare
5 - 7 September 2012 • Astana, Kazakhstan



TIHE
17th Uzbekistan International Healthcare Exhibition
24 - 27 April 2012 • Tashkent, Uzbekistan



BIHE
International Healthcare Exhibition
27 - 29 September 2012 • Baku, Azerbaijan



Beauty Uzbekistan
6th Uzbekistan International Beauty & AestheticMed
24 - 27 April 2012 • Tashkent, Uzbekistan



Stomatology Azerbaijan
International Stomatology Exhibition
27 - 29 September 2012 • Baku, Azerbaijan



Stomatology Uzbekistan
8th Uzbekistan International Dental Exhibition & Conference
24 - 27 April 2012 • Tashkent, Uzbekistan



Beauty Azerbaijan
International Beauty and Aesthetic Medicine Exhibition
27 - 29 September 2012 • Baku, Azerbaijan



Pharmacy/Pharmtech
7th Central Asian International Exhibition for Medicines,
Pharmaceuticals and Pharmaceutical Technology
24 - 27 April 2012 • Tashkent, Uzbekistan



Hospital
International Healthcare Exhibition
2 - 4 October 2012 • St. Petersburg, Russia



Stomatology
International Dental Exhibition & Conference
15 - 17 May 2012 • St. Petersburg, Russia



Pharmacy
International Pharmaceuticals Exhibition
2 - 4 October 2012 • St. Petersburg, Russia



KIHE
KIHE Kazakhstan International Healthcare Exhibition
16 - 18 May 2012 • Almaty, Kazakhstan



Public Health
International Healthcare Exhibition
23 - 26 October 2012 • Kiev, Ukraine



Medsib. SibDent
International Specialised Medical Exhibition
23 - 25 May 2012 • Novosibirsk, Russia



Dental-Expo St. Petersburg
International Dental Exhibition
30 October - 1 November 2012 • St. Petersburg, Russia



Medima
11th International Specialized Medical Exhibition
30 May - 1 June 2012 • Krasnodar, Russia



Pharmtech
International Pharmaceutical Production Exhibition
26 - 29 November 2012 • Moscow, Russia



Dentima
12th International Dental Forum
30 May - 1 June 2012 • Krasnodar, Russia



International Enquiries: Cornelia Limbach
Middle East, Egypt, India & Pakistan: Hossein Shariatmadar
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E: limbach@gima.de
E: hossein@ite-gulf.com
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1,250 companies in the healthcare industry meet in São Paulo / Brazil to introduce new products and technologies for hospitals



HOSPITALAR 2012

HOSPITALAR Fair and Forum is the most important annual meeting of the market and healthcare professionals in the Americas for updating. Companies from more than 30 countries present their novelties at the event

From May 22 – 25, entrepreneurs and professionals of the healthcare industry will gather in Sao Paulo / Brazil to participate in HOSPITALAR 2012 - 19th International Fair of Products, Equipment, Services and Technology for Hospitals, Laboratories, Pharmacies, Health Clinics and Medical Offices. The largest trade fair and healthcare forum in Brazil and the Americas covers a total of 82,000 m2 at the Expo Center Norte, a modern exhibition center; presenting new products, equipment and services, as well as debating management trends and development of the healthcare sector.

With the participation of 1,250 exhibiting companies, the 2012 edition of the fair is getting ready to host over 90,000 visitors, including heads of hospitals and clinics, nurses, physicians, medical professionals in general, distributors, manufacturers of the sector and international buyers. "The fair brings together the leading brands and major decision makers in the healthcare chain. It is the most important business and discussion platform of the sector in the Americas", says the founder and president of the HOSPITALAR, Waleska Santos, MD.

Thanks to the growing public and private investments, the Brazilian healthcare sector has shown an expansion in recent years. The market for equipment and medical, hospital and diagnostics products has finished 2011 with a growth of 19%, reaching revenues of US\$ 7.9 billion (R\$ 13.5 billion), higher than the average growth of the Brazilian economy. The sector also informs a record in the creation of new jobs, doubling the expectations for the period.

In this scenario, the HOSPITALAR Fair serves as the time for professional update and to generate business for the supplying industry. "The high qualification of the public and the good offer of novelties and innovations from the exhibitors generated business worth US\$ 3.5 billion (R\$ 6 billion) during the 2011 event, a result 11% higher than 2010. This confirms the strong growth of the healthcare market in Brazil", says the president.

International and globalized event

Companies from all over Brazil and several countries have made of HOSPITALAR a gateway to the Latin American healthcare market. In the 2011 edition, 525 companies were foreign exhibitors (30% of the total), representing 34 countries, namely, Canada, Chile, Denmark, France, Germany, The Netherlands, Switzerland, The United States. The international promotional campaigns for visitors also paid off, as the event hosted 4,700 buyers from 63 countries.

Healthcare Management Forum

Another highlight is the HOSPITALAR Forum, which brings together healthcare experts, entrepreneurs and professionals to discuss new concepts in management and optimization of financial and human resources. Altogether, congresses, seminars and workshops, represent over 60 events that attract an elite of thinkers, strategists and public and private healthcare managers, engaged in bringing forward new ideas for the development of the sector.

Renowned entities and official agencies of the sector support the HOSPITALAR Forum. Among them: National Health Confederation (CNS), Hospital Employers Association of the State of São Paulo – Brazil (SINDHOSP), Brazilian Medical Devices Manufacturers Association (ABIMO), Brazilian Medical Association (AMB), Brazilian Accreditation Organization (ONA), Regional Council of Nursing of São Paulo (COREN-SP), and others.

All about the fair: www.hospitalar.com

The Gateway To The 380 Million Consumer Market Of The East African Region

MEDEXPO 2012

The 16th MEDEXPO 2012 - International Trade Exhibition is the largest trade event held annually in Tanzania, the hub of the vast East African market. The exhibition attracts exhibitors from more than 20 countries and visitors from all over East & Central Africa, thus giving exhibitors an excellent opportunity to explore several countries in one time.

Over the past few years, Tanzania has emerged as a major regional trade centre. This is mainly due to a very friendly and business like atmosphere it offers to foreign investors and products. Duties are considerably low and re-exports to neighbouring countries are either very low or exempted.

Major Categories

- Hospital Supplies
- Healthcare
- Optical
- Medical Equipment
- Pharmaceuticals
- Dental

Why Tanzania?

Tanzania is regarded as one of the countries with the highest growth potential in Africa with enormous potential as an investment destination. It is one of the most promising emerging markets in the region, offering a unique combination of developed economic infrastructure and a vibrant emerging market economy.

Tanzania today is a land of countless business opportunities. Over the past two decades, it has been transformed from a centrally planned economy to a market oriented system through successful implementation of legal, regulatory and institutional reforms. The Government has encouraged private sector led growth through restoration of market forces and less interference in commercial activities. Overall, the reforms have resulted into positive growth trends and impressive macro-economic

indicators with inflation rates falling from 27.4% in 1995 to about 7% in 2007. Real GDP growth has averaged more than 7% during the last five years.

Tanzania is an economy increasingly oriented towards manufacturing and export. In 2007, the manufacturing sector grew by 8.7 percent compared to 8.6 percent in 2006, while the contribution of the sector to real GDP grew by 7.8 percent in 2007. The increase in growth was mainly attributable to increased production in sectors such as cement, beverages, corrugated iron sheets, steel products, cigarette, plastic products and textile.

Tanzania's manufacturing sector is already well integrated into the regional economy. The value of exports of manufactured goods increased by 58.0 percent to US\$ 309.2mn in 2007 from US\$ 195.8mn in 2006 mainly comprising of plastics, metals and apparels going to neighbouring countries of Rwanda, Burundi and the Democratic Republic of Congo.

Tanzania offers a well-balanced and competitive package of fiscal incentives in comparison with other African countries. Aiming at providing competitive fiscal regime on foreign trade, Tanzania has signed double taxation treaties with Denmark, India, Italy, Norway, Sweden, Kenya, Uganda, Zambia and Finland. Countries with which negotiations are continuing include South Africa, Republic of Korea, Zimbabwe, United Arab Emirates, Russia, Seychelles, Mauritius, Egypt, Yugoslavia and Oman.

Investments in Tanzania are guaranteed against nationalization and expropriation. Tanzania is a signatory of several multilateral and bilateral agreements on protection and promotion of foreign investment. Among other international agreements and membership, Tanzania is a member of Multilateral Investment Guarantee Agency (MIGA) and International Centre for Settlement of Investment Disputes (ICSID).

Tanzania's untapped natural resources offer a wide range of investment opportunities; arable land, minerals and natural tourist attractions are all awaiting potential investors. Tanzania is internationally renowned for its abundance of wildlife attractions and unexploited mineral reserves. These sectors (Mining and Tourism) are the leading recipient of foreign investment flow and are tipped to become the "growth sectors" of the economy.

Tanzania had been carrying out successful economic and structural reforms, which have improved economic performance and sustained growth. These achievements are based on solid foundations of political and economic reform undertaken by the Government since 1986, placing Tanzania in a position where a prolonged period of high GDP growth rates is expected. In addition, Tanzania has a stable fiscal regime with sustainable level of inflation.

For more information visit
www.expogn.com/tanzania/medexpo/index.php



KIMES 2012

978 companies from 30 countries worldwide

The largest North-East Medical Show showcased the advanced medical equipment.

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 28th KIMES, was held at COEX in Seoul from 16-19 March 2012, with hundreds of manufacturers showcasing their products.

The event filled 36,007sqm and showcased a wide range of products by 458 Korea manufacturers, USA 121, Japan 75, Germany 74, China 77 and many other international manufacturers.

The show itself has grown considerably over the past several years and it provides a platform not only for local market and the neighboring countries. Foreign participation was considerably larger than any time previously and is symbolic of a growing interest by foreign medical companies in this market. With such a large exhibitor base which covers the full breadth of the medical industry, KIMES stands as an important gauge of the direction the medical technology industry is taking. The Korean government appreciates the importance of this show and of the local medical industry for the Korean economy and on this basis provides significant support for KIMES.

Sponsors for the show included : Ministry of Knowledge Economy, Ministry of Health & Welfare, Seoul Metropolitan government, Korea Food and Drug Administration (KDA), Korea Trade Investment Promotion Agency. The unique Korean medical show was suggesting the direction for the future medical technology through 60,000 visitors who obtained information on all the current and future trends at the North-East Asia's premier medical event.



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.

KIMES 2012 will take place from March 21-24 2013

For more information visit KIMES website www.kimes.kr

Focus on The Medical Market in Canada

Enfoque
El mercado medical en Canada

General Figures:

**34,6
million**
Population

70%
Urbanization
rate

Median Total
income:
\$68,410

... Focus

2011 GDP
growth:
2.1%

2011 GDP:
**US\$1.57
trillion**

Source: Statistics Canada

7.2%
Unemployment rate

Foggy sunrise at Cape Spear
/ Shutterstock.com

Country Overview

The economy of Canada boasts one of the most **stable growth** patterns among Western economies, estimated at **2.1% in 2011**, as well as high ranks in almost all of the G7 charts as far as the **banking system and ease of doing business** are concerned. Canada's growth has, in fact, outpaced that of the other G7 economies in the last decades, thanks to sound fiscal policies and regulations.

Canada is an **export-led economy** with free trade agreements or foreign investment promotion and protection agreements concluded with 19 countries in the last six years. However, although the market-oriented profile, the government plays an important role in controlling the State's budget and taxation, allowing the provision of services such as employment insurance and old age security payments, as well as allocating resources for education, health and social services to the provinces.

Regulations and taxation are favourable to foreign investors thanks to the simple bureaucracy and reduced tariffs required to set up a business. Costs for doing research and bring new products onto the market are also reduced compared to other developed economies, with tax credits up to 30% available to companies investing in R&D activities.

The government strongly **supports research and development** with a total spending of US\$29.2 billion in 2010, increased by over 40% on the year 2000. Canada ranks 2nd among OECD countries in tax relief per R&D dollars spent and first among G7 countries for tax treatment of R&D when combined with the provincial tax support.

Some advantages offered by taxation policies are:

- corporate taxes for SMEs will be reduced from 19% to 15% by 2013
- federal sales tax has been reduced from 7% to 5%
- SR&ED (Scientific Research and Experimental Development) Tax Incentive Program encourages Canadian businesses of all sizes, and in all sectors to conduct R&D in Canada, providing cash refunds and/or tax credits up to 20% for companies' expenditures on eligible R&D work done in Canada.

The cities of **Montréal, Vancouver and Toronto** are among the **top 10 cities** in North America for life sciences patent filings, helped by a **reliable regulatory environment** and the **skilled and educated workforce**. Canada ranks first in the G7 countries for availability of qualified engineers, and second for university completion rates, as about a quarter working-age Canadians hold a university degree.

Healthcare system

The Canadian healthcare system has a peculiar profile, as it is:

- Based on universal health coverage with single payer arrangement
- Funded by the government through the "Medicare" public insurance program
- Delivered though public and private services

The **"Medicare" national health insurance program** grants all residents access to hospital and physician services, on a prepaid basis. 13 interlocking provincial and territorial health insurance plans, with certain common features and basic standards of coverage, provide coverage under the provisions of the Canada Health Act (CHA).

Descripción del país

La economía de Canadá cuenta con uno de los patrones más estables de crecimiento entre las economías occidentales que se estima en el 2,1% en el 2011, así como altos rangos en casi la totalidad de las listas del G-7 en lo que se refiere al sistema bancario y la facilidad de hacer negocios. El crecimiento de Canadá, de hecho, ha superado al de las demás economías del G-7 en las últimas décadas, gracias a sus políticas fiscales y reglamentos.

Canadá es una economía de exportación con acuerdos de libre comercio o de promoción de la inversión extranjera y acuerdos de protección firmados en 19 países en los últimos seis años. Sin embargo, aun con un perfil orientado al mercado, el gobierno desempeña un papel importante en el control del presupuesto del Estado y los impuestos, lo que permite la prestación de servicios tales como seguro de desempleo y los pagos de seguridad por vejez, así como la asignación de recursos para los servicios de educación, salud y asistencia social a las provincias.

Los reglamentos e impuestos son favorables a los inversionistas extranjeros gracias a la burocracia simple y reducción de los aranceles necesarias para establecer un negocio. Los costos para hacer investigación y traer nuevos productos al mercado también son reducidos en comparación con otras economías desarrolladas, con créditos fiscales de hasta un 30% a disposición de las empresas que invierten en actividades Investigación y Desarrollo.

El gobierno apoya la investigación y desarrollo con un gasto total de 29,2 billones de dólares americanos en el 2010, aumentado en más del 40% en el año 2000. Canadá clasifica segundo entre los países de la OCDE por beneficios fiscales para inversión de dólares en Investigación y Desarrollo y el primer lugar entre los países del G-7 en el tratamiento fiscal de Investigación y Desarrollo en combinación con el apoyo de los impuestos provinciales.

Algunas de las ventajas ofrecidas por las políticas fiscales son:

- los impuestos a la renta para las pymes serán reducidos del 19% al 15% en 2013
- el impuesto de ventas federal se ha reducido de 7% a 5%
- el SR & ED (Investigación Científica y Desarrollo Experimental) Programa de Incentivos de Impuestos anima a las empresas canadienses de todos los tamaños y en todos los sectores para llevar a cabo Investigación y desarrollo en Canadá, proporcionando reembolsos en efectivo y / o créditos fiscales de hasta un 20% de la inversión hecha a las empresas elegibles que trabajan en Investigación y desarrollo en Canadá.

Las ciudades de **Montreal, Vancouver y Toronto** se encuentran entre las **10 primeras ciudades de América del Norte** donde solicitar patentes en ciencias biológicas, ayudados por un entorno regulador fiable y una mano de **obra calificada y educada**. Canadá ocupa el primer lugar en los países del G-7 en disponibilidad de ingenieros calificados, y el segundo en las tasas de finalización de la universidad, ya que alrededor de un cuarto de los canadienses en edad de trabajar cuentan con un título universitario.

Sistema de salud

El sistema de salud canadiense tiene un perfil peculiar, ya que es:

- Basado en una cobertura universal de salud con el arreglo de un solo pagador
- Financiado por el gobierno a través del "Medicare", programa de seguro público
- Suministrado en los servicios públicos y privados



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Provincial and territorial insurance programs have to operate on a non-profit basis by a public authority and give all residents, even if they emigrate to a different province or territory, reasonable access to insured hospital, medical, and surgical-dental services.

The CHA requires provincial and territorial programs to disclose information on insured services to the federal Ministry of Health and grants less funding to programs allowing for extra-billing and user charges.

| Relevant Health Trends | 2003 | 2011 |
|---|--------|--------|
| Total personal expenditure on consumer goods and services | 686,55 | 980,63 |
| Total personal expenditure on medical care and health services | 35,44 | 57,88 |
| Medical care | 15,91 | 27,26 |
| Hospital care and the like | 1,65 | 2,77 |
| Other medical care expenses | 4,86 | 6,74 |
| Drugs and pharmaceutical products | 13,03 | 21,12 |
| % of all personal expenditure on medical care and health services | 5.2 | 5.9 |

Source: Statistics Canada

Healthcare Expenditure

Health care is largely funded by the government through taxes and out pocket contributions and private insurance; **public funding accounts for about 70%** of health care expenditure, while the private sector, which includes both private and out of pocket expenses, accounts for 30%. **Total health expenditures in Canada are estimated at roughly US\$200 billion.**

The **provinces and territories** administer and deliver most of Canada's **public health care services**, funded mainly through the Canadian Health and Social Transfer (CHST) program. Each provincial and territorial health insurance plan covers medically necessary hospital and doctors' services that are provided on a pre-paid basis, without direct charges at the point of service.

The federal government takes care of approximately one million people in special groups such as First Nations people living on reserves and Inuit, delivering primary care and emergency services on remote and isolated reserves and community-based health programs. These services are being increasingly delegated and integrated with the provincial and territorial systems.

The government also provides regulations and disease surveillance and prevention, as well as support for health promotion and research. Moreover, it has implemented tax credits for medical expenses, disability, caregivers and infirm dependants; tax rebates to public institutions for health services; and deductions for private health insurance premiums for the self-employed.

Private expenditure is mainly covered by **out-of-pocket** payments while private insurance covers about 41% of the costs of healthcare expenses not reimbursed by the government, according to Canadian Institute for Health Information (CIHI). Most of out-of-pocket spending is on prescription drugs and dental services excluded by public or private insurance programs. Canada's out-of-pocket spending level is around 15% of the total health expenditure.

El "Medicare" seguro nacional de salud garantiza a todos los residentes el acceso a los servicios médicos y hospitalarios, sobre una base prepagada. 13 planes de enclavamiento de salud provinciales y territoriales de seguros, con ciertas características comunes y normas básicas de cobertura, proporcionan la cobertura según las disposiciones de la Ley de Salud de Canadá (CHA).

Los programas de seguros provinciales y territoriales tienen que operar sobre una base sin ánimo de lucro, por medio de una autoridad pública y dar a todos los residentes, incluso si emigran a una provincia o territorio diferente, el acceso razonable a un hospital asegurado, a un médico, y a los servicios quirúrgico dentales.

La CHA exige a los programas provinciales y territoriales divulgar información sobre los servicios de seguros a la Secretaría de Salud federal y otorga menos fondos a los programas que permiten cargos extra de facturación y al usuario.

Gastos en asistencia sanitaria

La atención de la salud es en gran parte financiada por el gobierno a través de impuestos y contribuciones y los seguros privados. Las cuentas públicas de financiación equivalen a alrededor del 70% del gasto sanitario, mientras que el sector privado, que incluye tanto gastos privados como los gastos extra adicionales, representa el 30%. **Los gastos totales de salud en Canadá se estima en los \$ 200 mil millones aproximadamente.**

Las provincias y territorios administran y ofrecen la mayor parte de los servicios de salud pública de Canadá, financiados principalmente a través del Programa de Salud y de Transferencia Social de Canadá (CHST). Cada plan de seguro de salud provincial y territorial abarca los servicios médico sanitarios necesarios de hospitalización que se proporcionan sobre una base pre-pago, sin cobro directo en el punto de servicio.

El gobierno federal se hace cargo de aproximadamente un millón de personas en los grupos especiales, tales como los que viven en reservas First Nation e Inuit, brindando la prestación de atención primaria y los servicios de emergencia en las reservas remotas y aisladas y en las comunidades basadas en programas de salud. Estos servicios son cada vez más delegados y se integran con los sistemas provinciales y territoriales.

El gobierno también establece normas, vigilancia y prevención de enfermedades, así como el apoyo para la promoción de la salud y la investigación. Por otra parte, ha puesto en marcha los créditos fiscales para los gastos médicos, en caso de discapacidad, a cuidadores y personas dependientes y a enfermos; rebajas fiscales a los organismos públicos para los servicios de salud, y deducciones para las primas de seguros médicos privados para los trabajadores autónomos.

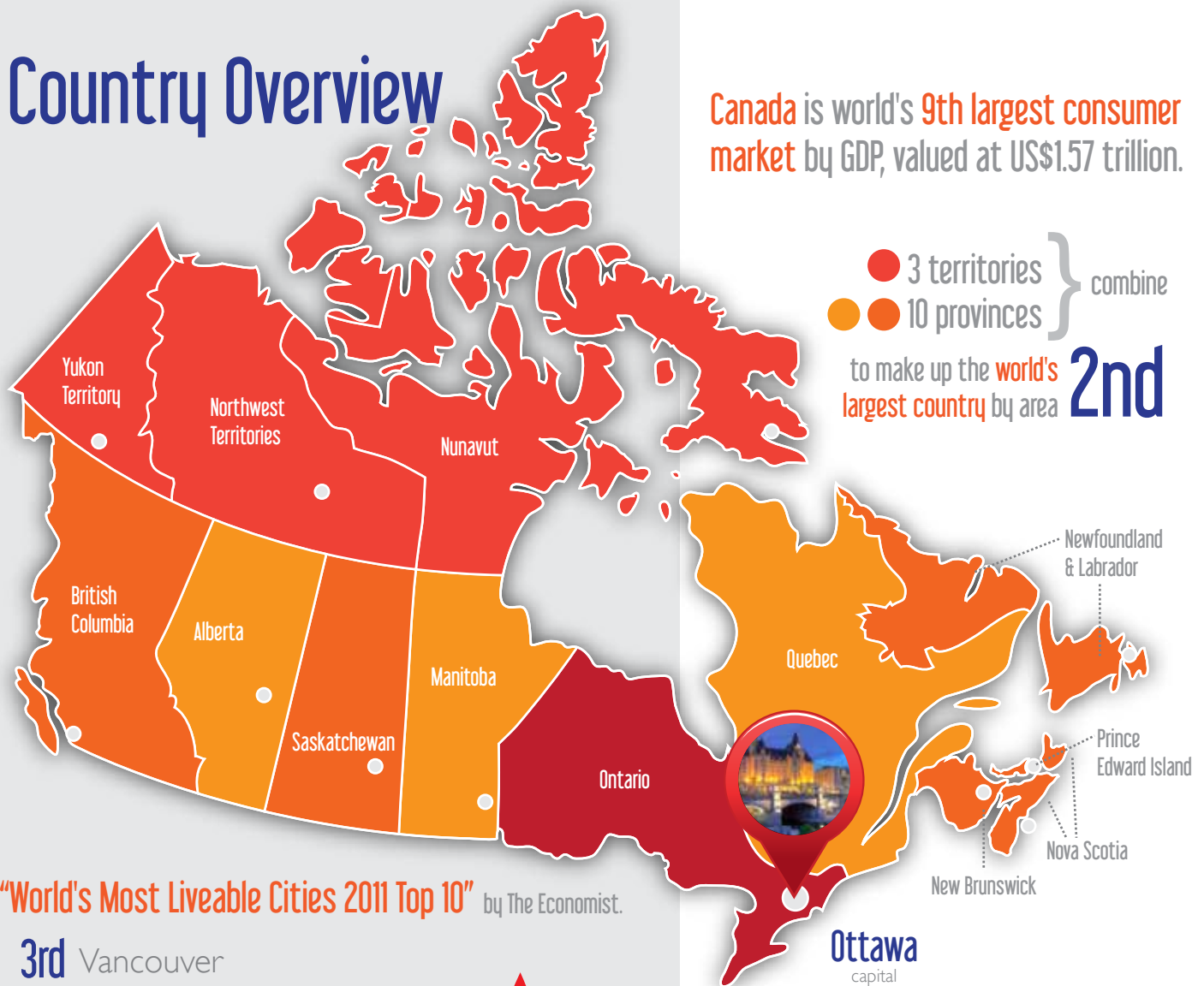
El gasto privado es principalmente cubierto por los pagos en efectivo mientras que el seguro privado cubre alrededor del 41% de los costos de gastos médicos no reembolsados por el gobierno, de acuerdo con el Instituto Canadiense de Información de Salud (CIHI).

La mayor parte de los gastos en efectivo son en medicamentos recetados y servicios dentales excluidos de los programas de seguro público o privado. El nivel de gasto en efectivo en Canadá es alrededor del 15% del total del gasto en salud.

Desafíos: Las políticas nacionales de reducción de la deuda requieren cortar los gastos de asistencia sanitaria, debido principalmente a los hospitales, medicamentos y médicos. Para hacer frente a la carga que pesa sobre el

Country Overview

Canada is world's **9th largest consumer market** by GDP, valued at US\$1.57 trillion.



"World's Most Liveable Cities 2011 Top 10" by The Economist.

3rd Vancouver

4th Toronto

5th Calgary



Democratic constitutional monarchy



Queen Elizabeth II
formal head of State

&

an elected Prime Minister
Stephen Harper as head
of Government.



Under the federal system of **parliamentary government**, responsibilities and functions are shared between:

- federal government
- provincial government
- territorial government

More densely populated cities:

1

Toronto, economic capital and one of the world's leading financial centres, cosmopolitan city.

2

Montreal, Francophone Canadian province of Quebec, world's second largest French-speaking city after Paris, Canada's cultural capital.

3

Vancouver, largest port in Canada, third film production centre in North America after Hollywood and New York.

4

Calgary, oil and petrochemical industry.

5

Edmonton, another important center for the oil and petrochemical industry.

Challenges: National debt reduction policies require cutting the costs for health care, mainly due to hospitals, prescription drugs and physicians. To address the burden placed on the health system by the aging population, the government is also focusing on promoting healthier lifestyles, increasing access to medical services, and moving to an outcome-driven fee payment system.

Canadian health care spending, 2010

Hospitals (funding operations) 29%
 Prescription Drugs 16%
 Physicians 14%
 Dental Services 7%
 Capital Investment 4%
 Health Research 2%
 Other 28%

Canadian private health care spending, 2010

Dental Services 23%
 Hospitals 9%
 Vision Care 8%
 Other 59% (Prescribed Drugs 25%, Physicians 1%, Capital 2%, Other 30%)

Canadian health care spending by Province, 2010

Alberta 12%
 British Columbia 13%
 Quebec 21%
 Ontario 40%
 Other 15% (Manitoba 4%, Saskatchewan 3% Nova Scotia 3%, New Brunswick 2%, Newfoundland & Labrador 3%)

Ontario and Quebec, the two most populous provinces, account for over 60% of all health care spending.

sistema de salud por el envejecimiento de la población, el gobierno también se centra en la promoción de estilos de vida saludables, incrementar el acceso a los servicios médicos, y en pasar a un sistema de tarifas de pago basado en los resultados.

Gastos en Asistencia sanitaria en Canadá en el 2010

Hospitales (Financiación de las operaciones) 29%
 Medicamentos con receta 16%
 Médicos 14%
 Servicios Dentales 7%
 Inversiones del Capital 4%
 Investigación en Salud 2%
 Otros 28%

Gastos en Asistencia sanitaria privada en Canadá en el 2010

Servicios Dentales 23%
 Hospitales 9%
 Cuidado de la Visión del 8%
 Otro 59% (25% Medicamentos recetados, Médicos del 1%, 2% de capital, otros 30%)

Gastos en Asistencia sanitaria por provincia en Canadá en el 2010

Alberta 12%
 Columbia Británica 13%
 Quebec 21%
 Ontario 40%
 Otro 15% (4% de Manitoba, Saskatchewan, Nueva Escocia el 3% 3%, 2% Nuevo Brunswick, Terranova y Labrador 3%)

Ontario y Quebec, las dos provincias más pobladas, representan más del 60% del gasto total en atención de la salud.

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The Market for Medical Devices and Products

Canadian medical devices industry

According to data reported in the Government portal "Industry Canada", the country's medical devices industry is valued at **US\$7 billion**, growing at a compound annual rate (CAGR) of 2% from 2000 to 2008, and forecast to maintain 5-6 % growth over the next few years, reaching \$8.6 billion <by 2015.

The sector counts more than **1,500 companies employing some 35,000 people**. Small firms with less than 25 employees make up to 57% of the medical equipment companies, while 37% have 25 to 49 employees and about 4% are medium-sized. Firms with more than 150 employees are only 1%. Approximately 90% of companies are Canadian owned.

Manufacturing companies are highly diversified, consisting mainly of small and medium sized enterprises focusing on high-end products thanks to close cooperation with other industries such as biotechnology, advanced materials, microelectronics and IT.

A peculiar characteristic of the Canadian medical industry is its closeness to research environments and universities. It is estimated that 10% of the medical device companies are spin-offs from universities, other firms or laboratories.

Although their number is limited, large multinationals lead the market through distribution bases and sales force, while only a few have manufacturing facilities in Canada. Sales channel are dominated by large importing distributors and buying groups such as retail pharmacies chains who sell directly to health facilities.

El mercado de dispositivos médicos y productos

La industria canadiense de dispositivos médicos

De acuerdo con datos reportados en el portal de Gobierno "Industry Canada", la industria médica de dispositivos del país, tiene un valor de **\$ 7 billones de dólares**, creciendo a una tasa anual compuesta (CAGR) del 2% entre el 2000 y 2008, y prevé mantener un 5-6% de crecimiento en los próximos años, alcanzando \$ 8.6 mil millones en el 2015.

El sector cuenta con más de **1.500 empresas que emplean a unas 35.000 personas**. Las pequeñas empresas con menos de 25 empleados representan el 57% de las empresas de equipos médicos, mientras que el 37% tienen de 25 a 49 empleados y cerca de un 4% son de tamaño medio. Las empresas con más de 150 empleados son sólo el 1%. Aproximadamente el 90% de las empresas son de propiedad canadiense.

Las empresas de fabricación están muy diversificadas, consisten principalmente en empresas pequeñas y medianas que se centran en la gama productos de alta calidad, gracias a la estrecha cooperación con otras industrias como la biotecnología, materiales avanzados, la microelectrónica y la informática.

Una característica peculiar de la industria médica de Canadá es su cercanía a los ambientes de investigación y universidades. Se estima que el 10% de las empresas de dispositivos médicos son spin-offs de las universidades, otras empresas o laboratorios.

Aunque su número es limitado, las grandes multinacionales lideran el mercado a través de bases de distribución y fuerza de ventas, mientras que sólo unos pocos tienen instalaciones de fabricación en Canadá. Los canales

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The medical industry is concentrated in the provinces of Ontario and Quebec, together accounting for 80%, and British Columbia. Since medical equipment spending is driven by public funding, government spending policies in these provinces make budget allocated for medical technology and equipment quite stable over time.

Medical import-export

Canada's exports of medical devices increased at a CAGR of 5.5% from 2000 to 2009 (from \$1.6 billion in 2000 to \$2.6 billion in 2009). During the same period, import growth was also strong although lower at a CAGR of 4.6%. **On general terms, Canada imports more medical devices than it exports:** in 2009 Canada exported a total value of US\$2.6 billion while importing US\$5.1 billion, with a trade deficit of \$2.5 billion.

The United States account for roughly 2/3 of Canadian medical device exports, in spite of a decreasing trend due to the appreciation of the Canadian dollar and economic recession, as well as to the competing pressure coming from emerging medical manufacturing countries. However, there is an increasing diversification of destination markets for Canadian medical devices, such as Germany, UK and the Netherlands.

USA are also the main source of medical equipment imports but Germany, Japan and China are expanding their market shares. The US share in medical imports has actually decreased from 68% in 2000 to 51% in 2009, while China, Mexico and Ireland have doubled their share, and Germany and Switzerland also increased their sales. All together these five countries represent about one quarter of the import market.

The main sectors of innovation for Canadian firms are cardiovascular devices, medical imaging, in vitro diagnostics, dental implants and materials, and assistive devices for home health care.

Disposable equipment and supplies are the largest export category (around 50%) followed by electro-surgical devices (25%), Imaging equipment (20%) and home care products (5%).

de ventas están dominados por los grandes distribuidores de importación y grupos de compra, tales como las cadenas de farmacias que venden directamente a los establecimientos de salud.

La industria médica se concentra en las provincias de Ontario y Quebec, que sumaron el 80%, y la Columbia Británica. Dado que el gasto de equipos médicos es impulsada por la financiación pública, las políticas de gasto del gobierno en estas provincias presupuesto asignado para la tecnología médica y equipos bastante estable en el tiempo.

Importación-exportación médica

Las exportaciones canadienses de dispositivos médicos aumentaron a una tasa compuesta anual del 5,5% entre 2000 y 2009 (de \$1,6 billones en el 2000 a \$2,6 billones en el 2009). Durante el mismo período, el crecimiento de las importaciones fue también fuerte, aunque menor en un CAGR de 4,6%. **En términos generales, Canadá importa más productos sanitarios que los que exporta.** En el 2009 Canadá exportó un valor total de \$2,6 billones de dólares, mientras que importó 5,1 billones, con un déficit comercial de US \$ 2,5 billones.

Los Estados Unidos representan aproximadamente 2/3 de las exportaciones canadienses de dispositivos médicos, a pesar de una tendencia decreciente debido a la apreciación del dólar canadiense y la recesión económica, así como a la presión de la competencia procedente de manufacturación médica de países emergentes. Sin embargo, hay una creciente diversificación de los mercados de destino para los dispositivos médicos canadienses, tales como Alemania, Reino Unido y los Países Bajos.

Los EE.UU. son también la principal fuente de importaciones de equipos médicos, pero Alemania, Japón y China están ampliando sus cuotas de mercado. La participación de EE.UU. en las importaciones médicas ha disminuido de un 68% en el 2000 al 51% en 2009, mientras que China, México e Irlanda han duplicado su cuota, y Alemania y Suiza también incrementaron sus ventas. Todos juntos, estos cinco países representan aproximadamente una cuarta parte del mercado de importación.

| Top Ten Exports | Share of Total Exports |
|---|------------------------|
| Sanitary articles of paper | 22.2% |
| Composite diagnostic or laboratory reagents | 11% |
| Opacifying prep, X-ray; diagnostic reagents | 8.9% |
| Medical, surgical, dental or veterinary furniture | 6.6% |
| Instruments and appliances used in medical or veterinary sciences | 6.2% |
| Parts and accessories for application based on the use of X-rays | 5.3% |
| Electro-diagnostic apparatus | 4.1% |
| Mechano-therapy application; massage applications | 3.9% |
| Electro-cardiographs | 3.4% |
| Needles, catheters, cannulae and the like | 3.00% |
| Top Ten Exports total share: | 74.3% |
| | (\$1.9 billion) |

Source: Statistics Canada, World Trade Atlas 2009

| Top Ten Imports | Share of Total Imports |
|--|------------------------|
| Instruments and appliances used in medical, surgical procedures | 9.1% |
| Diagnostic reagent for medical diagnosis | 8% |
| Bougies, catheters, drains and sondes, and parts and accessories thereof | 4.2% |
| Mechano-therapy application | 4.2% |
| Appliances, which are worn or carried or implanted in the body | 3.5% |
| Cannulae | 3.4% |
| Instruments and appliances, used in dental science | 3.2% |
| Ozone, oxygen or aerosol therapy | 3.1% |
| Sunglasses, corrective, protective or other | 2.8% |
| Syringes, with or without needles | 2.6% |
| Top Ten Imports | 41.9% (\$bn 2.2) |
| All other HS codes | 58.1% (\$bn 2.86) |

Source: Statistics Canada, World Trade Atlas 2009

Canada has the lowest costs for establishing and operating a medical device manufacturing facility in the G7

Profile of Canada's medical industry by sector

Disposable Equipment and Supplies

- Strongest sub-segment are diagnostic reagents and supplies (60% of exports)
- In Vitro-Diagnostics supported by research community, market is fragmented and highly competitive

Electro-medical Devices

- exports close to US\$700 million in 2009
- mainly intended for exports, while most of the devices in the Canadian market are imported (US\$602 million in 2009)
- Government initiative "10 year plan to strengthen healthcare" supporting manufacture and imports of minimally invasive medical technologies and imaging devices

Diagnostic Imaging equipment

- reliant on imported technologies (US\$500 million in 2009)
- market controlled by three largest groups accounting for 80% of the market: GE Healthcare, Philips Medical Systems and Siemens Medical Solutions
- fastest growing segment is CT equipment, with growth rate of 26%
- industry trends are multimodality imaging on the same equipment and mobile medical imaging devices

Home Care Market

- dominated by imports (US\$1.5 billion in 2009)
- supported by public policies aimed at shortening hospital stays, improve efficiency of financial resources and enabling elderly people to enjoy better autonomy

Profile of medical industry clusters across Canada's provinces

British Columbia

- Employs about 2,700 people and generates annual revenues of approximately \$800 million;
- More than 60 medical-device manufacturing and distribution companies;

Los principales sectores de la innovación para las empresas canadienses son dispositivos cardiovasculares, el diagnóstico in vitro, implantes dentales y materiales, y dispositivos de ayuda para el cuidado de salud en el hogar.

El equipo desechable y suministros son la principal categoría de exportación (alrededor del 50%), seguido de dispositivos electro-quirúrgicos (25%), equipos de representación óptica de la imagen (20%) y productos de cuidado del hogar (5%).

Perfil de la industria médica de Canadá por sector

Equipos Desechables y Suministros

- El sub-segmento más fuerte son los reactivos de diagnóstico y suministros (60% de las exportaciones)
- Diagnóstico In Vitro apoyados por la comunidad de investigación, el mercado está fragmentado y es altamente competitivo

Dispositivos médicos

- las exportaciones de cerca \$ 700 millones en el 2009
- destinados principalmente a las exportaciones, mientras que la mayoría de los dispositivos en el mercado canadiense se importan (\$ 602 millones en 2009)
- iniciativa del gobierno de la " plan de 10 años para fortalecer la salud", el apoyo a la fabricación y la importación de tecnologías médicas mínimamente invasivas y dispositivos de imagen

Equipos de diagnóstico por imagen

- dependen de las tecnologías importadas (\$ 500 millones en 2009)
- mercado controlado por tres más grandes grupos que cubren el 80% del mercado: GE Healthcare, Philips Medical Systems y Siemens Medical Solutions
- el segmento de más rápido crecimiento es un equipo de TC, con una tasa de crecimiento del 26%
- las tendencias de la industria son la multimodalidad de imagen en el mismo equipo y los dispositivos móviles de tratamiento de imágenes médicas

Mercado Cuidado en el Hogar

- dominado por las importaciones (\$ 1.5 billones en 2009)
- con el apoyo de políticas públicas orientadas a acortar las escancias hospitalarias, mejorar la eficiencia de los recursos financieros y permitir a las personas de edad avanzada disfrutar de mayor autonomía

Mountain landscape

Pichugin Dmitry / Shutterstock.com

- Areas of specialty: interventional and implantable cardiology, diagnostic and therapeutic ultrasound, and diagnostic testing, design and development of orthopaedic devices;
- Investment of \$1.5 billion in the province's science infrastructure, combined with significant investments in R&D, and support from Simon Fraser University's 4D Labs research centre on advanced materials and nanoscale devices.

Alberta

- More than 80 firms, mostly located in Edmonton and Calgary and surrounding areas;
- Areas of specialty: wound care, personal protective equipment, medical diagnostics, and medical imaging technologies;
- Support to research from institutions such as the National Institute for Nanotechnology, the National Research Council Institute for Biodevices and the universities of Alberta, Calgary, and Lethbridge.

Manitoba

- Winnipeg hosts a cluster of companies specialized in magnetic resonance imaging (MRI) and medical assistive devices for institutional and retail markets;
- Cutting-edge research in MRI and other non-invasive surgical technologies is conducted at the National Research Council Institute for Biodevices, the St. Boniface General Hospital Research Centre, the University of Manitoba's Health Sciences Centre and the Centre for the Commercialization of Biomedical Technology.

Ontario

- Medical- and assistive-device industry based in Ottawa and Toronto, with subsidiaries of multinationals including Abbott Point of Care, Agfa and GE Healthcare;
- Areas of specialty: medical imaging, robotics, and e-health;
- Education centre with 24 colleges and 20 universities, graduating 29,000 students a year in mathematics, engineering and sciences
- Internationally recognized research institutes: Toronto's MaRs Centre, teaching hospitals, the University of Toronto with affiliated research institutes, the Neurochip Consortium (global partnership of university research groups and companies assessing results of testing of drug effects on neuronal activity)

Québec

- More than 350 companies, clustered in Montréal;
- Areas of specialty: radiology, cardiology, orthopaedics, oncology, obstetrics, clinical decision assistance, dentistry, and remote surgery;
- Innovation and research supported by the National Research Council of Canada Industrial Materials Institute as well as by innovative companies and global med-tech leaders.

Nova Scotia

- Research and technology cluster composed of universities, community colleges, hospitals, and government labs engaged in life-sciences
- Location of Brain Repair Centre, a multidisciplinary facility that links more than 100 world-class researchers and physicians.

Foreign investment in Canada's Life Sciences sector

Over 65% of all Life Science investments in Canada are made by foreign sources, mainly in Quebec and Ontario. Investment funding in medical technologies in Canada is preferably directed to medical imaging (about 60% of the total). Among the competitive advantages offered by Canada to invest in the medical sector there are:

- high number of experienced researchers, with close to 35,000 researchers in Montréal alone, and another 40,000 in Toronto and Vancouver combined;

Perfil de los grupos de la industria médica en las provincias de Canadá

Colombia Británica

- Da empleo a unas 2.700 personas y genera ingresos anuales de aproximadamente \$ 800 millones;
- Más de 60 dispositivos médicos de fabricación y empresas de distribución;
- Las áreas de especialidad: cardiología intervencionista e implantables, ultrasonido de diagnóstico y terapéutico, las pruebas de diagnóstico, diseño y desarrollo de dispositivos ortopédicos;
- Inversión de \$ 1.5 billones en infraestructura científica de las provincias, junto con importantes inversiones en Investigación y Desarrollo, y el apoyo de los laboratorios de investigación en 4D del centro de la Universidad Simon Fraser en materiales avanzados y dispositivos a nanoescala.

Alberta

- Más de 80 empresas, ubicadas principalmente en Edmonton y Calgary y sus alrededores;
- Las áreas de especialidad: el cuidado de heridas, equipo de protección personal, el diagnóstico médico, y las tecnologías de imágenes médicas;
- Apoyo a la investigación de instituciones como el Instituto Nacional de Nanotecnología, el Consejo Nacional de Investigación, Instituto de Biodiagnóstico y las universidades de Alberta, Calgary y Lethbridge.

Manitoba

- Winnipeg alberga un grupo de empresas especializadas en la resonancia magnética (MRI) y dispositivos de asistencia médica para los mercados institucionales y al por menor;
- La investigación de vanguardia en la resonancia magnética y otras tecnologías no invasivas de cirugía se lleva a cabo en el Instituto Nacional de Investigación del Consejo de Biodiagnóstico, Centro de Investigación del Hospital General de San Bonifacio, Centro de Ciencias de la Universidad de Salud de Manitoba y el Centro para la Comercialización de la Tecnología Biomédica.

Ontario

- La industria médica y de asistencia de dispositivos con sede en Ottawa y Toronto, con las filiales de las multinacionales como Abbott Point of Care, Agfa y GE Healthcare;
- Las áreas de especialidad: imágenes médicas, robótica, y e-salud;
- Centro de Educación con 24 colegios y 20 universidades, donde se gradúan 29.000 estudiantes al año en las matemáticas, la ingeniería y las ciencias
- Institutos de investigación reconocidos internacionalmente: MARS Centre de Toronto, hospitales universitarios, la Universidad de Toronto con los institutos afiliados de investigación, el Consorcio Neurochip (asociación mundial de grupos de investigación universitarios y empresas de evaluación de resultados de las pruebas de los efectos de los fármacos en la actividad neuronal)

Québec

- Más de 350 empresas, agrupadas en Montreal;
- Las áreas de especialidad: radiología, cardiología, ortopedia, oncología, obstetricia, asistencia de decisión clínica, odontología y cirugía a distancia;
- La innovación e investigación apoyadas por el Consejo Nacional de Investigación de Canadá del Instituto Industrial de Materiales, así como por las empresas innovadoras y líderes mundiales de tecnología de medicina.

Nueva Escocia

- Grupos de la investigación y la tecnología integrados por universidades, colegios comunitarios, hospitales y laboratorios gubernamentales dedicados a la ciencias de la vida
- Ubicación del Centro de Reparación Cerebral, un centro multidisciplinar que une a más de 100 investigadores de talla mundial y los médicos.

- The lowest costs for establishing and operating a medical device manufacturing facility in the G7
- Canada is the first G-20 country to eliminate tariffs on all manufacturing inputs

Medical Device investment levels by segment, 2008:

- 27% Surgical Devices
- 18% Diagnostic Equipment (not Imaging)
- 10% Implantable Medical Devices
- 3% Medical Imaging Equipment
- 42% Other Medical Devices

Government funding for medical research and development

Government funding is allocated through grants and subsidies, generally allocated at the provincial level for SMEs for research and commercialization activities, as well as through tax credits, and direct and indirect investment in companies. The provincial and federal governments have shifted from direct investments towards co-investments or indirect investments program, through fund of funds programs, among which there are:

The National Research Council of Canada Industrial Research Assistance Program (NRC-IRAP) Provides financial support through matching funds and loans to qualified small and medium-sized enterprises in Canada to help with development costs for new technologies.

Health Technologies Exchange (HTX)

Provides access to funding sources for both technology start-ups and well established international companies that have manufacturing operations in Ontario.

Alberta Innovates - Health Solutions (AIHS)

Funding program for promoting health research and commercialization activities.

Other direct investments are done through the Business Development Bank of Canada (BDC) helping SMEs to grow their business and expand into new markets and at the provincial level through investment funds supporting the commercialization of innovative technologies such as the Alberta IVAC Capacity Builder, and Ontario Investment Accelerator Fund (IAF).

Canada is the first G-20 country to eliminate tariffs on all manufacturing inputs

Regulation of Medical Devices

Health Canada, through the Medical Devices Bureau of the Therapeutic Products Directorate, is the federal regulator of therapeutic products including medical devices, in accordance with the Food and Drugs Act and Regulations and the Medical Devices Regulations. Health Canada reviews medical devices before authorizing their sale in Canada. The Canadian medical device regulations (CMDR) categorize medical devices based on risk as Class I, II, III, or IV.

Manufacturers of medical devices sold in Canada must obtain licenses through the Therapeutic Products Directorate's Medical Devices Bureau, and also be listed in the Medical Device Active License Listing (MDALL). All medical devices except for Class I devices require Medical Device Active License, and moderate- to high-risk devices must also meet ISO 13485 quality system requirement.

La inversión extranjera en el sector de las ciencias biológicas de Canadá

Más del 65% de todas las inversiones en ciencias biológicas en Canadá se hacen por fuentes extranjeras, principalmente en Quebec y Ontario. El financiamiento de las inversiones en las tecnologías médicas en Canadá se dirige preferentemente a las imágenes médicas (alrededor del 60% del total).

Entre las ventajas competitivas que ofrece Canadá para invertir en el sector médico se encuentran:

- elevado número de investigadores experimentados, con cerca de 35.000 investigadores solo en Montreal y otros 40.000 en Toronto y Vancouver combinados;
- Los costos más bajos para establecer y operar una instalación de fabricación de dispositivos médicos en el G-7
- Canadá es el primer país del G-20 en eliminar los aranceles sobre todos los insumos de fabricación

Niveles de inversión en dispositivos médicos por segmento, en el 2008:

- 27% dispositivos quirúrgicos
- 18% de equipos de diagnóstico (no de imagen)
- 10% de los productos sanitarios implantables
- 3% de equipos de imágenes médicas
- 42% Otros dispositivos médicos

Fondos para la investigación médica y el desarrollo del gobierno

El financiamiento del gobierno se asigna a través de ayudas y subvenciones, por lo general asignados a nivel provincial para las PYME, para las actividades de investigación y comercialización, así como a través de créditos fiscales y de inversión directa e indirecta en las empresas. Los gobiernos provincial y federal han pasado de las inversiones directas hacia las co-inversiones o al programa de inversión indirecta, a través del fondo de los programas de fondos, entre los cuales se encuentran:

El Programa de Asistencia para la Investigación Industrial del National Research Council de Canadá (NRC-IRAP) Proporciona apoyo financiero a través de fondos de contrapartida y préstamos cualificados a las pequeñas y medianas empresas en Canadá para ayudar con los costos de desarrollo de las nuevas tecnologías.

Tecnologías para la Salud de Valores (HTX)

Proporciona acceso a las fuentes de financiación tanto para la tecnología de creación de empresas bien establecidas y las empresas internacionales que tienen operaciones de fabricación en Ontario.

Alberta Innova - Soluciones para la Salud (AIHS)

Programa para la financiación y la promoción de la investigación en salud y comercialización de las actividades.

Otras inversiones directas se realizan a través del Banco de Desarrollo de Negocios de Canadá (BDC) para ayudar a las PYME a hacer crecer sus negocios y expandirse a nuevos mercados y en el ámbito provincial a través de fondos de inversión de apoyo a la comercialización de tecnologías innovadoras tales como el promotor de la capacidad de Alberta IVAC, y Acelerador de Inversiones del Fondo de Ontario (IAF).

Regulación de Dispositivos Médicos

Health Canada, a través de la Oficina de Dispositivos Médicos de la Dirección de Productos Terapéuticos, es el regulador federal de los productos terapéuticos, incluyendo dispositivos médicos, de conformidad con la Ley y el Reglamento de Alimentos y Medicamentos y el Reglamento de Productos Sanitarios.

Health Canada revisa los dispositivos médicos antes de autorizar su venta en Canadá. Las regulaciones canadienses de dispositivos médicos (CMDR) categorizan los dispositivos médicos basados en el riesgo como clase I, II, III o IV.

Lowest-risk devices (Class I devices) do not require such licensing, but manufacturers, distributors and importers of Class I devices who intend to sell directly in Canada, and not through a licensed importer or distributor, must obtain a Medical Device Establishment License (MDEL). The MDEL identifies establishments that are selling or manufacturing devices and requires them to provide assurance of compliance to regulatory requirements related to post-production activities.

The Bureau maintains a database of all licensed Class II, III, and IV medical devices offered for sale in Canada. Only products which appear in this database listing may be marketed in Canada.

Two basic licenses issued by Health Canada

Health Canada Medical Device Establishment License (MDEL)

- required for Class I medical device manufacturers, importers and distributors if selling directly into Canada. If a company sells through distributors in Canada, they must have a MDEL
- not required for Class II, III and IV manufacturers

Health Canada Medical Device License (MDL):

- required for companies which manufacture, import or distribute Class II, III, and IV medical devices in Canada is a product approval different from MDEL (permit for the company/distributor itself)
- requires proof of certified ISO 13485:2003 quality system meeting the specific requirements of the Canadian Medical Device Regulations (CMDR)

Medical device review process

1. Submission of a Medical Device Licence Application to the Therapeutic Product Directorate.
2. If the information provided meets the requirements of the Medical Devices Regulations, a Licence is issued. The target average review time goes from 15 days for Class II Licence applications to 75 and 90 days for Class III and IV Licence applications respectively.
3. If the TPD denies the License, the manufacturer may re-submit the application with additional information or appeal the TPD's decision.
4. TPD monitors medical devices' safety and effectiveness after they are licensed, and may suspend the Licence or require the manufacturer to recall or refit the medical device.

Update: Increased fees as of April 1, 2012

Health Canada plans to increase fees to manufacturers of Class II, III and IV medical devices, as well as for Medical Device Establishment License (MDEL) and renewal fees.

For further information please refer to Canada Gazette (<http://gazette.gc.ca/rp-pr/p1/2012/2012-02-18/html/notice-avis-eng.html#d104>)

Sources:

Statistics Canada - www.statcan.gc.ca

Invest in Canada - <http://investincanada.gc.ca>

Health Canada - www.hc-sc.gc.ca

OSEC, "The Canadian Medical Technology Sector", February 2011 - www.osec.ch

Emergo Group, "Canada Medical Device License (MDL) Approvals and Registration" - www.emergogroup.com

Los fabricantes de dispositivos médicos vendidos en Canadá deben obtener licencias a través de los equipos de emergencia de la Oficina Médica de la Dirección de dispositivos, y también se encuentran en el Listado de licencias producto sanitario activo (MDALL). Todos los productos sanitarios, excepto los dispositivos de Clase I requieren de licencia de producto sanitario activo, y los dispositivos de moderado a alto riesgo, también deben cumplir con los requisitos del sistema de calidad de la norma ISO 13485.

Canadá es el primer país del G-20 en eliminar los aranceles sobre todos los insumos de fabricación

Los dispositivos de menor riesgo (de dispositivos de Clase I) no requieren de licencia tal, pero los fabricantes, distribuidores e importadores de dispositivos de Clase I que tengan la intención de vender directamente en Canadá, y no a través de un importador o distribuidor autorizado, deben obtener una licencia de establecimiento de Dispositivos Médicos (mdel). El mdel determina los establecimientos que se venden o fabrican dispositivos y les obliga a garantizar el cumplimiento de los requisitos reglamentarios relacionados con las actividades de post-producción.

La Oficina mantiene una base de datos de todas las licencias de dispositivos médicos Clase II, III y IV que se ofrecen a la venta en Canadá. Sólo los productos que aparecen en este listado de bases de datos podrán ser comercializados en Canadá.

Dos licencias básicas emitidas por Health Canada

Licencia de Establecimiento de Dispositivos Médicos, Health Canada (mdel)

- requerido para la clase I, los fabricantes de dispositivos médicos, importadores y distribuidores si la venta directamente en Canadá. Si una empresa vende a través de distribuidores en Canadá, que debe tener un mdel
- no es necesario para los fabricantes de la clase II, III y IV,

Licencia Médica de dispositivos, Health Canada (MDL):

- es necesario para las empresas que fabrican, importan o distribuyen dispositivos médicos de la clase II, III, IV en Canadá la aprobación de producto diferente de mdel (permiso para la empresa / distribuidor sí mismo)
- requiere la prueba el cumplimiento de los requisitos específicos del sistema de calidad certificado ISO 13485:2003 de los Reglamentos de Dispositivos Médicos de Canadá (CMDR)

Dispositivos médicos proceso de revisión

1. Presentación de una solicitud de licencia de dispositivo médico a la Dirección de Productos Terapéuticos.
2. Si la información proporcionada cumple con los requisitos de los Reglamentos de Dispositivos Médicos, una licencia es emitida. El tiempo de revisión promedio va de 15 días para las solicitudes de licencias de la Clase II de 75 y 90 días para las aplicaciones de licencia de clase III y IV, respectivamente.
3. Si el TPD niega la licencia, el fabricante puede volver a presentar la solicitud con información adicional o apelar la decisión del TPD.
4. TPD controla los dispositivos de seguridad y la eficacia de los médicos después de que se licencian, y podrá suspender la licencia o obligar al fabricante a retirar del mercado o volver a montar el dispositivo médico.



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Medical markets in Central America

Los mercados médicos
en América Central

Bahamas

Population
340,000
(2008 est.)

Life
Expectancy:
74 years

Capital City:
Nassau

Literacy rate:
96.6%

Infant Mortality
rate:
**3 deaths/
1000
live births**
(2011 est)

Government:
**parliamentary
democracy,**
*member of
Commonwealth*

GDP (at market prices):
**US\$ 7.538
billion (2010 est)**

Country Facts

Green sea turtle
Shutterstock.com

Bahamas

The Bahamas consist of 700 islands, 29 of which are inhabited, and over 2,000 rocks and cays. 85% of the population in the Bahamas lives on two major islands, New Providence, where the capital Nassau is located, and Grand Bahamas. The Bahamas is an English speaking country, which gained its independence from Britain on July 10, 1973.

The Bahamas enjoys a **stable democratic environment** and is member of the Caribbean Basin Initiative (CBI), Canada's CARIBCAN Program, and the European Union's Economic Partnership Agreement. Foreign investment in tourism, banking, agricultural and industrial areas that generate local employment is encouraged. Tourism contributes 22% of The Bahamas' GDP. Financial services, the second most important sector, account for up to 15% of GDP while agriculture and industry together account for less than 10% of GDP. While the country's largest export is service, some commodities such as chemicals, plastic goods, pharmaceuticals and industrial salt are produced for export.

The Bahamas has regular air and sea transportation with the United States and telecommunication service is also generally adequate, while mail service is slow both among the islands and with other countries. **Customs duties are high** as the Bahamian Government raises over 50% of its total revenue from import tariffs. The basic ad valorem tariff for imported goods is 35%, but many items have separate tariff rates. Import Licenses are required for imports of medical devices, whose application should be made at the Ministry of Health.

A large proportion of third-country products are imported through the United States, usually through Florida. **The healthcare system consists of both public and private sectors.** The Government provides tax-funded, free of charge healthcare at public clinics and health centres, to all civil servants, children, pregnant women and persons aged 60 or above. If necessary, the Government contracts and subsidizes private sector services. Private care, instead, is funded by direct user fees or private insurers. Hospitals are located in the major islands and equipped with the latest technology as well as supported by highly trained medical professionals. However, under certain medical conditions or circumstances, the patient has to be transferred to the United States for treatment. The geographic fragmentation challenges makes it difficult to access healthcare in some of the smaller islands, where the only facilities are small clinics with inadequate resources. Therefore, some of the islands have their own emergency response services on a voluntary base who administer emergency medical treatment and transport of patients to the nearest hospital.

| Medical device | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------------------|---------------|----------------|-------|--------------------------------|
| Magnetic Resonance Imaging | - | 1 | 1 | 0.3 |
| Computerized Tomography Scanner | 2 | 3 | 5 | 1.4 |
| Mammograph | 2 | 2 | 4 | 7.1 |
| Linear accelerator | - | 1 | 1 | 0.3 |

Source: WHO

Bahamas

Las Bahamas consiste de 700 islas, de las cuales 29 están habitadas, y más de 2.000 rocas y cayos. 85% de la población vive en las Bahamas en dos islas principales, New Providence, donde se encuentra la capital Nassau, y la Isla de Gran Bahamas. Las Bahamas es un país de habla Inglés, que obtuvo su independencia de Gran Bretaña el 10 de julio de 1973.

Las Bahamas cuenta con un entorno democrático estable y es miembro de la Iniciativa de la Cuenca del Caribe (ICC), el Programa de CARIBCAN del Canadá, y el Acuerdo de Asociación Económica de la Unión Europea. La inversión extranjera en el turismo, la banca y las zonas agrícolas e industriales que generen empleo local son estimuladas. El turismo constituye el 22% del PIB de las Bahamas. Los servicios financieros, el segundo sector más importante, representan hasta el 15% del PIB mientras que la agricultura y la industria en conjunto representan menos del 10% del PIB. Mientras que la mayor exportación del país son los servicios, algunos productos tales como productos químicos, materias plásticas, productos farmacéuticos y la sal industrial, se producen para la exportación.

Las Bahamas cuenta con transporte marítimo y aéreo con los Estados Unidos y el servicio de telecomunicaciones es en general eficiente, mientras que el servicio de correo es lento, tanto entre las islas y con otros países. **Los derechos de aduana son altos** porque el Gobierno de las Bahamas obtiene más del 50% de sus ingresos totales de aranceles de importación. El arancel ad valorem de base para las mercancías importadas es del 35%, pero que muchos artículos tienen tasas arancelarias separadas. Licencias de importación se requieren para la importación de dispositivos médicos, cuya aplicación debe hacerse en el Ministerio de Salud. Una gran proporción de productos de terceros países se importan a través de los Estados Unidos, generalmente a través de la Florida. **El sistema de salud se compone de los sectores público y privado.** El Gobierno ofrece la asistencia sanitaria gratuita financiada con los impuestos, en las clínicas públicas y centros de salud, a todos los funcionarios, niños, mujeres embarazadas y las personas mayores de 60 años o más. Si es necesario, el gobierno contrata y subsidia los servicios del sector privado. La atención privada, en cambio, está financiado por cuotas de los usuarios directos o los aseguradores privados.

Los hospitales se encuentran en las islas mayores y están equipadas con la última tecnología, así como el apoyo de profesionales médicos altamente capacitados. Sin embargo, bajo ciertas condiciones médicas o circunstancias, el paciente tiene que ser transferido a los Estados Unidos para recibir tratamiento. Los desafíos de la fragmentación geográfica hace que sea difícil acceder a la asistencia sanitaria en algunas de las islas más pequeñas, donde las únicas instalaciones son pequeñas clínicas con insuficientes recursos. Por lo tanto, algunas de las islas tienen sus propios servicios de respuesta de emergencia en una base voluntaria, que administran el tratamiento médico de emergencia y el transporte de los pacientes al hospital más cercano.

Health resources

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 150 | n/a | 150 | 43.8 |
| Provincial hospital | 2 | 1 | 3 | 0.8 |
| Regional hospital | 1 | - | 1 | 0.2 |

Source: WHO

Costa Rica

Literacy rate:

94%

Population
in poverty:

18.3%

Average per
capita income:

US\$10,569

Population:

4.6 million
(2009 est.)

Infant
mortality rate:

9.45 per
1,000
live births
(2011)

Life
expectancy:

Men
75.1 years,
Women
80.5 years
(2011)

Unemployment
rate:

6.7%

Capital City:
San José

Foreign direct
investment, 2010:

US\$1.45 billion

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Expansion of health services

Last March, the Public Hospitals Authority has acquired the **Island Palm Hotel on Grand Bahama to expand services at the adjacent Rand Memorial Hospital with a \$1.9 million deal**. The Island Palm Hotel is expected to increase bed capacity at the Rand Memorial Hospital from 82 to at least 150 beds, including some private beds. It will also allow Rand Memorial to expand a number of critical areas such as laboratory services and facilitate the use of tele-radiology as part of the tele-medicine thrust in the future.

Moreover, a \$75 million health care project has already begun in November 2011 with the redevelopment of the **Princess Margaret Hospital in Nassau** beginning by the construction of a critical care unit. The hospital is expected to become a 500-bed facility inclusive of a dedicated maternal and child-care wing, while non-core medical services will be relocated away. The redevelopment project also includes a new entryway to the hospital inclusive of building codes recommended by the American Disability Association, and critical utility upgrades.

The block will provide for the consolidation of laboratory facilities, an increased number of operating theatres, improved storage and increased availability of beds in the Intensive Care and Neonatal Intensive Care units.

The completion of the first phase is expected to take 24 months. The Royal Bank of Canada provided a \$55-million loan to the Public Hospitals Authority (PHA), the public corporation responsible for the management and development of the public hospital system in the Commonwealth of The Bahamas. The government will pick up the tab for the remaining \$20 million.

Construction of this new facility will also provide opportunities for the employment of 130 or more Bahamians, exclusive of physicians and nurses, to be trained to become surgical and orthopaedic, radiology, pharmacy, rehabilitation, intensive care, laboratory, biomedical, EKG and ECHO technicians. Additionally, medical records, patient care aides, maintenance technicians and other service officers are required, providing opportunities for a range of entrepreneurs and service providers.

Medical Tourism

The Bahamas are a medical tourism destination with high quality facilities and proximity to the U.S. makes it one of the top destinations for patients looking for exceptional medical care and a wonderful country. Some of the most popular procedures offered are Cardiac Surgeries, Total Knee/Hip Surgery Replacements, Cosmetic & Plastic Surgery and much more.

Costa Rica

The services sector accounts for about 68% of GDP. **Costa Rica enjoys the region's highest standard of living** and is considered to be the most "developed" of the Central American countries because it has a relatively high GDP per capita and has the best indicators for life expectancy at birth, infant mortality rate, and adult literacy rate.

The government supports sustainable development and established protected national parks or reserves covering around 25% of the country's land area. Nevertheless, deforestation has been a serious concern, and insufficient funding is dedicated to enforcement of environmental laws.

La expansión de los servicios de salud

En marzo pasado, la Autoridad de Hospitales Públicos ha adquirido la **Isla Palm Hotel en Grand Bahama para ampliar los servicios del adyacente Rand Memorial Hospital con un contrato de \$ 1.9 millones**. La isla Palm Hotel se espera que aumente la capacidad de camas en el Hospital Rand Memorial, de 82 a al menos 150 camas, incluyendo algunas de camas privadas. Asimismo, permitirá a Rand Memorial expandir una serie de áreas críticas, tales como servicios de laboratorio y facilitar el uso de la tele-radiología como parte de la idea central de telemedicina en el futuro.

Por otra parte, un proyecto de atención a la salud \$ 75 millones ya se ha iniciado en noviembre de 2011 con la remodelación del Hospital Princess Margaret en Nassau; en principio con la construcción de una unidad de cuidados intensivos. En el hospital se espera que sea incluido un centro de 500 camas y de un ala dedicada a la atención materna e infantil, mientras que los servicios médicos no esenciales serán reubicados de inmediato. El proyecto de reurbanización incluye también una nueva entrada al hospital con los códigos de construcción recomendadas por la Asociación Americana de Discapacidad y con las actualizaciones críticas a los servicios públicos. El bloque se encargará de la consolidación de las instalaciones de laboratorio, un aumento del número de quirófanos, la mejora del almacenamiento y la mayor disponibilidad de camas en la Terapia Intensiva y Unidades de Cuidados Intensivos Neonatales.

La finalización de la primera fase se espera que dure 24 meses. El Royal Bank de Canadá otorgó un préstamo de \$ 55 millones a la Autoridad Pública de Hospitales (PHA), la empresa pública responsable de la gestión y el desarrollo del sistema de hospitales públicos en el Commonwealth de las Bahamas. El gobierno va a pagar los restantes \$ 20 millones.

La construcción de este nuevo servicio también ofrecerá oportunidades de empleo para 130 o más bahameses, sin contar los médicos y enfermeras, entrenados para convertirse en técnicos quirúrgicos y ortopédicos, en radiología, farmacia, rehabilitación, cuidados intensivos, laboratorios, biomédicos, y EKG y ECHO. Además, de los registros médicos, auxiliares de atención al paciente, técnicos de mantenimiento y otros funcionarios de servicio se requeridos, ofreciendo oportunidades para una serie de empresarios y proveedores de servicios.

Turismo Médico

Las Bahamas son un destino de turismo médico, con instalaciones de alta calidad y la proximidad a los EE.UU. lo convierte en uno de los principales destinos para los pacientes que buscan atención médica excepcional y un país maravilloso. Algunos de los procedimientos más populares que se ofrecen son cirugías cardíacas, cirugía total de rodilla, prótesis de cadera, cirugía estética y plástica y mucho más.

Costa Rica

El sector servicios representa cerca del 68% del PIB. **Costa Rica goza de más alto nivel de vida de la región** y es considerado como el más "desarrollado" de los países centroamericanos, ya que tiene un PIB per cápita relativamente alto y tiene los mejores indicadores para la esperanza de vida al nacer, tasa de mortalidad infantil y la tasa de alfabetización de adultos.

El gobierno apoya el desarrollo sostenible y estableció parques nacionales o reservas protegidos que cubren alrededor del 25% de la superficie terrestre del país. Sin embargo, la deforestación ha sido una preocupación seria, y la insuficiencia de fondos se dedica a la aplicación de las leyes ambientales.

Public Health Care

Public health insurance system, commonly known as the Caja (Caja Costarricense de Seguro Social, CCSS), is available to all Costa Rica's citizens and legal residents. Ten major public hospitals, of which four are located in San Jose, including the Children's Hospital, are affiliated with the Caja. For non-emergencies and everyday medical care, small clinics, known as EBAIS, are located in almost every community. CCSS insurance costs approximately 10 to 11.5% of income, but residents may also opt for ARCR, which provides a streamlined and simple joining process. All persons aged under 55 are required a pension payment that is collected by Caja to be disbursed beginning at age 65.

Private Insurance

Private insurance plans available through INS, the government-owned insurance company, include dental work, optometry, wellness visits and annual check-ups. Prescription drugs, certain medical exams, sick visits and hospitalization are covered at 80% cost, and surgeon and aesthetician costs are covered at full cost. Currently, private medical insurance costs about \$60-\$130/month per person, depending on age, gender and other factors.

| Medical devices | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------------------|---------------|----------------|-------|--------------------------------|
| Magnetic Resonance Imaging | -2 | 1 | 3 | 0.06 |
| Computerized Tomography Scanner | 7 | 7 | 14 | 0.3 |
| Nuclear medicine | 4 | 1 | 5 | 0.1 |
| Mammograph | 20 | 4 | 24 | 3.6 |
| Linear accelerator | 2 | 3 | 5 | 0.1 |
| Telecobalt unit (Cobalt-60) | 3 | - | 3 | 0.06 |

Source: WHO

Health resources

| Healthcare facility | Public sector | Private sector | Total | Density per 100,000 population |
|---------------------|---------------|----------------|-------|--------------------------------|
| Health post | 103 | n/a | 32 | 2.2 |
| Health centre | 29 | 3 | 13 | 0.7 |
| District hospital | 13 | n/a | 11 | 0.3 |
| Provincial hospital | 7 | 4 | 14 | 0.2 |
| Regional hospital | 9 | 5 | | 0.3 |

Source: WHO

Cuidado de la Salud Pública

El sistema público de salud, conocido comúnmente como la Caja (Caja Costarricense del Seguro Social, CCSS), está disponible para todos los ciudadanos de Costa Rica y residentes legales. Diez grandes hospitales públicos, de los cuales cuatro se encuentran en San José, entre ellos el Hospital de Niños, están afiliados a la Caja. Para lo que no constituye una emergencia y atención médica todos los días, clínicas pequeñas, conocidos como EBAIS, se encuentran en casi todas las comunidades.

El seguro de la CCSS tiene un coste aproximado de 10 a 11,5% de los ingresos, pero los residentes también pueden optar por el ARCR, que ofrece un proceso simplificado y sencillo para unirse. Todas las personas menores de 55 deben pagar las pensiones que se recogen mediante la Caja y que son desembolsadas a partir de las 65 años de edad.

Seguros Privados

Planes de seguros privados disponibles a través del INS, la empresa estatal de seguros, incluyen el trabajo dental, optometría, las visitas de bienestar anuales y chequeos. Los medicamentos con receta, ciertos exámenes médicos, visitas medicas y hospitalización están cubiertos en un 80% de los costos y los gastos de cirujano y esteticista están cubiertos completamente. En la actualidad, los costos del seguro médico privado son de alrededor de \$60 a \$130 al mes por persona, dependiendo de la edad, el género y otros factores.

Arenal volcano in Costa Rica with a plume of smoke

Tony Northrup / Shutterstock.com

Medical device industry

Costa Rica is a hub for medical device manufacturing, with many North American companies partnering with local enterprises. There are 25 medical devices companies in Costa Rica including world leaders Hospira, Boston Scientific, Cytec-Hologic, Arthrocare, Allergan, and Coloplast. The industry employs 6,300 people and is the 4th largest exporting industry in Costa Rica.

In March, Oberg Medical, a full-service medical device contract manufacturer providing implants, instruments, and complex assemblies, announced plans for expansion of its Costa Rica manufacturing operation to better serve the expanding medical device market in Central America and provide cost optimization solutions for US OEMs.

Costa Rica's private hospitals and clinics offer high-quality medical care at much lower costs than in the US and other Latin American countries. For instance, the Joint Commission International (JCI) has accredited three hospitals in San Jose.

Moreover, the country's proximity to the United States, political stability, highly ranked healthcare system and quality private health facilities make it a prime destination for medical tourism. In 2010 36,000 medical tourists travelled to Costa Rica, mainly from the United States and Canada, seeking cosmetic surgery, orthopaedics, weight loss surgery, gynaecology, and dental procedures.

La industria de dispositivos médicos

Costa Rica es un centro de fabricación de dispositivos médicos, con muchas empresas norteamericanas asociadas con empresas locales. Hay 25 empresas de dispositivos médicos en Costa Rica, incluyendo los líderes mundiales de Hospira, Boston Scientific, Hologic Cytec, Arthrocare, Allergan, y Coloplast. La industria emplea a 6.300 personas y es la cuarta mayor industria de exportación en Costa Rica. En marzo, Oberg médica, un fabricante médico de dispositivos tales como implantes, instrumentos y ensamblajes complejos, anunció sus planes de expansión en Costa Rica para servir mejor al creciente mercado de dispositivos médicos en Centroamérica y ofrecer soluciones y optimización de costes para la EE.UU.

Los hospitales privados de Costa Rica y clínicas ofrecen atención médica de alta a costos mucho más bajos que en los EE.UU. y otros países de América Latina. Por ejemplo, la Joint Commission International (JCI) ha acreditado a tres hospitales en San José. Por otra parte, la proximidad del país a los Estados Unidos, la estabilidad política, el sistema de salud de alto rango y la calidad de las instalaciones privadas de salud lo convierten en un destino privilegiado para el turismo médico. En 2010, 36.000 turistas médicos viajaron a Costa Rica, principalmente de los Estados Unidos y Canadá, en busca de la cirugía estética, ortopedia, cirugía de pérdida de peso, ginecología y procedimientos dentales.

Sources:

Foreign & Commonwealth Office – www.fco.gov.uk

WHO “Baseline country survey on medical devices”

– www.who.int/medical_devices/countries/bhs.pdf

Council for the International Promotion of Costa Rica Medicine PROMED

– www.promed.com

Medical Tourism Association – www.medicaltourism.com



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World economic outlook

IMF Marks Down Global Growth Forecast, Sees Risk on Rise

- IMF says global recovery expected to stall, risks to intensify
- Euro area expected to fall into mild recession, rest of world to slow
- Comprehensive package needed to restore financial stability
- Countries should avoid too rapid tightening of fiscal policy

With intensifying strains in the euro area weighing on the global outlook, the International Monetary Fund (IMF) has sharply cut its forecast for world growth this year, saying prospects have dimmed and risks to financial stability have increased.

In an update to its World Economic Outlook (WEO), the IMF said that the euro area would fall into a mild recession in 2012 after the euro area crisis entered a "perilous new phase" toward the end of last year, affecting other parts of the world including the United States, emerging markets, and developing countries.

Overall, activity in the advanced economies is now projected to expand by just 1.2 percent in 2012—a downward revision of $\frac{3}{4}$ percentage points relative to the forecast last September—picking up to a still tepid 1.9 percent the next year.



The global growth outlook for this year is 3.3 percent

"Given the depth of the 2009 recession, these growth rates are too sluggish to make a major dent in very high unemployment," the IMF said.

With the revised forecast, the IMF also released updates on January 24 to its Global Financial Stability Report (GFSR), which tracks issues in banking and capital markets, and its Fiscal Monitor, which tracks government debt and budgets.

Europe is epicenter

"The outlook for growth is mediocre, and it could be worse," said Olivier Blanchard, the IMF's Economic Counsellor.

At a press conference in Washington D.C., Blanchard said that "the world recovery, which was weak in the first place, is in danger of stalling. The epicenter of the danger is Europe, but the rest of the world is increasingly affected." He told reporters there was an even greater danger if the European crisis intensified. "In this case, the world could be plunged into another recession," he said.

But Blanchard said that with the right set of measures, "the worst can definitely be avoided, and the recovery can be put back on track. These measures can be taken, need to be taken, and need to be taken urgently."

In a speech in Berlin on January 23, IMF Managing Director Christine Lagarde laid out the main elements of a policy path forward. Europe, which is at the center of global concerns, needs stronger growth, larger firewalls, and deeper integration, she said, but added that other economies also have an important role to play to restore balanced global growth. As for the multilateral component, Lagarde said that the IMF was ready to help and was seeking to increase its lending resources by up to \$500 billion.

Asia still strong

The report said in 2012–13, growth in emerging and developing economies is expected to average $5\frac{3}{4}$ percent—a significant slowdown from the $6\frac{3}{4}$ percent growth registered in 2010–11, and about $\frac{1}{2}$ percentage point lower than projected in the September 2011 WEO.

This reflects the deterioration in the external environment, as well as the slowdown in domestic demand in key emerging economies. Despite a substantial downward revision of $\frac{3}{4}$ percentage point, developing Asia is still projected to grow most rapidly at $7\frac{1}{2}$ percent on average in 2012–13.

Economic activity in the Middle East and North Africa is expected to accelerate in 2012–13, driven mainly by the recovery in Libya and the continued strong performance of other oil exporters. Most oil-importing countries in the region face muted growth prospects due to longer than expected political transition and an adverse external environment. The impact of the global slowdown on sub-Saharan Africa has to date been limited to a few countries, most notably South Africa, and the region's output is expected to expand by about $5\frac{1}{2}$ percent in 2012. The adverse spillover effects are expected to be the largest for central and eastern Europe, given the region's strong trade and financial linkages with the euro area economies.

The impact on other regions is expected to be relatively mild, as macroeconomic policy easing is expected to largely offset the effects of slowing demand from advanced economies and rising global risk aversion. For many emerging and developing economies, the strength of the forecasts also reflects relatively high commodity prices.

Europe key to restoring confidence

Blanchard said that growth in the euro area in 2012 was now forecast at -0.5%, a decrease of 1.6% relative to the IMF's September 2011 projection. "In particular, we predict negative growth of 2.2% in Italy, 1.7% in Spain," he said.

The IMF said the most immediate policy challenge is to restore confidence and put an end to the crisis in the euro area by supporting growth, while sustaining fiscal adjustment, containing deleveraging, and providing more liquidity and monetary accommodation.

In other major advanced economies, the key policy requirements are to address medium-term fiscal imbalances and to repair and reform financial systems, while sustaining the recovery. In emerging and developing economies, near-term policy should focus on responding to moderating domestic growth and to slowing external demand from advanced economies.



Financial sector risks rise

In its GFSR update, the IMF said global financial stability has moved deeply into the danger zone as sovereign bond spreads in the euro area have widened, and the European Central Bank has been forced to play an increasingly vital role in sustaining the euro area financial system. Despite the efforts of European policymakers to contain the euro area debt crisis and related banking problems, a comprehensive and decisive policy response is still needed, the IMF said.

"European policymakers need to promptly put in place a comprehensive package that restores confidence, and need to implement the policy measures agreed at the October and December euro zone summits," said José Viñals, the IMF's Financial Counsellor and head of the Monetary and Capital Markets Department.

The IMF said officials should create a large firewall designed to protect sovereigns that are solvent but facing financing strains. Although institutions intended for this purpose exist, they currently do not have the size and flexibility required to be fully credible.

Banks need to increase their capital to restore financial markets' confidence in their ability to weather the downturn. Wherever possible, this should be done by raising capital from private sources, but public funding should be available for this purpose when needed. There should also be a pan-euro-area facility with the capacity to take direct stakes in banks.

Officials need to monitor the adjustment of bank balance sheets in the face of the crisis, and act to prevent "bad" deleveraging—asset sales that have the effect of reducing the supply of credit to the economy. Officials should aim to limit deleveraging of their banks not only in home markets but also abroad.

The IMF added that despite the resilience demonstrated in recent years by emerging markets, they face risks from deleveraging by euro area banks, particularly in emerging Europe countries.

Progress on fiscal side

Fiscal deficits in many advanced economies fell significantly during 2011, and most plan substantial adjustment this year. Continued adjustment is necessary for medium-term debt sustainability, and should ideally occur at a pace that supports adequate growth in output and employment, according to the latest Fiscal Monitor.

"The pace of fiscal consolidation in advanced economies in 2012 is already high," said Carlo Cottarelli, head of the IMF's Fiscal Affairs Department, which produced the report. "Too rapid consolidation, if economic growth slows, could exacerbate risks."

Most countries should allow automatic stabilizers, such as unemployment insurance payments that rise as jobs are eliminated, to work if growth slows. When economic conditions deteriorate they can cushion the impact on demand.

Countries that have the fiscal space, including some in Europe, could consider slowing the pace of consolidation this year. Some countries, notably the United States and Japan, need to clarify their plans to reduce debts and deficits in the years ahead.

Some emerging economies with low debt and deficits and declining inflationary pressure have room to make policy more supportive of economic activity. Others have little space for more than the operation of automatic stabilizers if growth slows.

Emerging economies highly dependent on commodity revenues and external capital inflows also need to consider the risk of a large and protracted decline in these flows.

Source:



Author: IMF- International Monetary Fund

Publication: IMF Survey Magazine

Website: www.imf.org

IMF - International Monetary Fund

The International Monetary Fund (IMF) is an organization of 187 countries, working to foster global monetary cooperation secure financial stability, facilitate international trade, promote high employment and sustainable economic growth and reduce poverty around the world.

Latest IMF projections

The IMF projects that the world economy will grow 3.3 percent this year, substantially slower than its estimate four months ago.

| | Projections | | | | Difference from September 2011 WEO Projections | |
|--|-------------|------|------|------|--|------|
| | 2010 | 2011 | 2012 | 2013 | 2012 | 2013 |
| World Output | 5.2 | 3.8 | 3.3 | 3.9 | -0.7 | -0.6 |
| Advanced Economies | 3.2 | 1.6 | 1.2 | 1.9 | -0.7 | -0.5 |
| United States | 3.0 | 1.8 | 1.8 | 2.2 | 0.0 | -0.3 |
| Euro Area | 1.9 | 1.6 | -0.5 | 0.8 | -1.6 | -0.7 |
| Germany | 3.6 | 3.0 | 0.3 | 1.5 | -1.0 | 0.0 |
| France | 1.4 | 1.6 | 0.2 | 1.0 | -1.2 | -0.9 |
| Italy | 1.5 | 0.4 | -2.2 | -0.6 | -2.5 | -1.1 |
| Spain | -0.1 | 0.7 | -1.7 | -0.3 | -2.8 | -2.1 |
| Japan | 4.4 | -0.9 | 1.7 | 1.6 | -0.6 | -0.4 |
| United Kingdom | 2.1 | 0.9 | 0.6 | 2.0 | -1.0 | -0.4 |
| Canada | 3.2 | 2.3 | 1.7 | 2.0 | -0.2 | -0.5 |
| Other Advanced Economies | 5.8 | 3.3 | 2.6 | 3.4 | -1.1 | -0.3 |
| Newly Industrialized Asian Economies | 8.4 | 4.2 | 3.3 | 4.1 | -1.2 | -0.3 |
| Emerging and Developing Economies | 7.3 | 6.2 | 5.4 | 5.9 | -0.7 | -0.6 |
| Central and Eastern Europe | 4.5 | 5.1 | 1.1 | 2.4 | -1.6 | -1.1 |
| Commonwealth of Independent States | 4.6 | 4.5 | 3.7 | 3.8 | -0.7 | -0.6 |
| Russia | 4.0 | 4.1 | 3.3 | 3.5 | -0.8 | -0.5 |
| Excluding Russia | 6.0 | 5.5 | 4.4 | 4.7 | -0.7 | -0.4 |
| Developing Asia | 9.5 | 7.9 | 7.3 | 7.8 | -0.7 | -0.6 |
| China | 10.4 | 9.2 | 8.2 | 8.8 | -0.8 | -0.7 |
| India | 9.9 | 7.4 | 7.0 | 7.3 | -0.5 | -0.8 |
| ASEAN-5 * | 6.9 | 4.8 | 5.2 | 5.6 | -0.4 | -0.2 |
| Latin America and the Caribbean | 6.1 | 4.6 | 3.6 | 3.9 | -0.4 | -0.2 |
| Brazil | 7.5 | 2.9 | 3.0 | 4.0 | -0.6 | -0.2 |
| Mexico | 5.4 | 4.1 | 3.5 | 3.5 | -0.1 | -0.2 |
| Middle East & North Africa (MENA) | 4.3 | 3.1 | 3.2 | 3.6 | ... | ... |
| Sub-Saharan African | 5.3 | 4.9 | 5.5 | 5.3 | -0.3 | -0.2 |
| South Africa | 2.9 | 3.1 | 2.5 | 3.4 | -1.1 | -0.6 |

*Indonesia, Malaysia, Philippines, Thailand and Vietnam

SOURCE: IMF, World Economic Outlook, January 2012.



How to access the Brazilian Medical Market

With a combined population of more than 310 million inhabitants and a growing market, Brazil continues to be a very attractive destination for companies linked to the field of general health, such as makers of medical devices, medications, general care, cosmetics, food supplements.

President Dilma Rousseff campaigned on a strong healthcare platform and continues to make this issue a top priority of her government.

In Brazil there are two points of access to health services. The public, governed by the Single Health System (SUS) and private health insurance represented by (plano de Saúde) which allow access to the private system.

Both systems are thriving: the public because of the government's efforts to retool and restructure hospitals and clinics, in addition to a boom in construction of new health centers and delivery systems, and the private due to the rise in Brazilians standard of living, which allows them to purchase plans with fewer burdens and easier accessibility.

The growth of the cosmetics industry alone is truly outstanding. Brazil is now the world's third largest cosmetics market in general and the first for deodorants and other body care products. While some global brands are already present, there are still many new consumers and niche markets to tap. Opportunities that many foreign companies are beginning to understand and explore.

ANVISA – Brazil's National Agency for Sanitary Vigilance controls everything that relates to health and personal care products and extends to surveillance of its ports, airports, and points of sale. Everything that relates to general health, including vitamins and food supplements, cosmetics and medicines is overseen by ANVISA. This control includes the manufacture, import and export of these products.

To ensure traceability, Brazilian law requires the production, manufacturing, importing, exporting and sales of any medical, pharmaceutical and cosmetic products may only be handled by local (Brazilian) authorized companies. Foreign businesses must go through a lengthy registration process with ANVISA in addition to obtaining licenses to sell their products within that country. To complicate the process, some

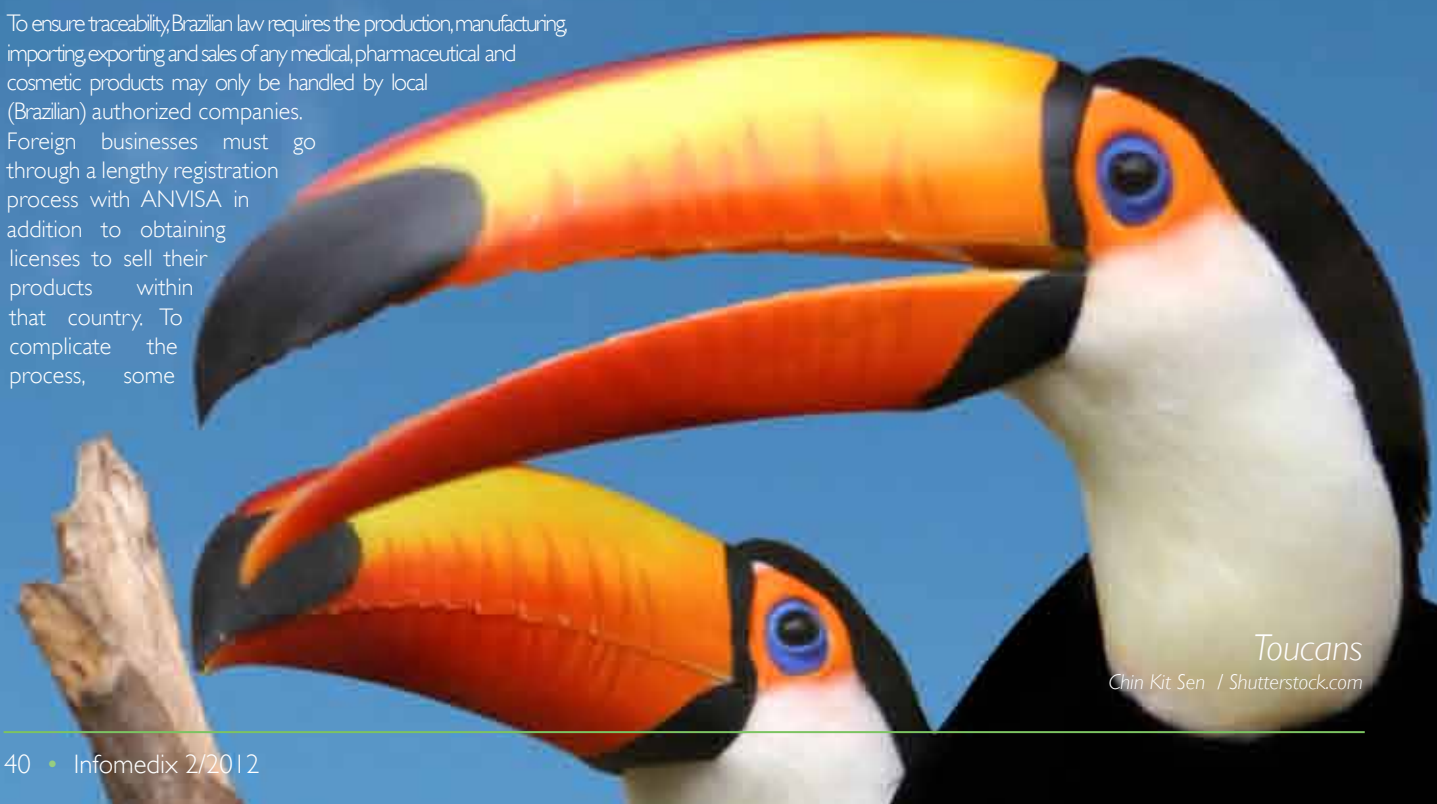
products are evaluated on their risk classifications, similar to the USA's Food and Drug Administration or the European Medicines Agency, but particular to Brazil. This certification takes the form of an audit by ANVISA technicians, carry out an on-site audit of physical facilities and all manufacturing processes and quality controls used by the manufacturer before delivery. Most manufacturers will also have to comply with specific certificates or accreditations such as Good Manufacturing Practices (GMP).

The length of time between filing an application for registration and final approval by the government is considerable, given the existing queue. It is not uncommon for the process to take more than 16 months. By the time that all regulatory and legal steps are carried out successfully, obtaining the Brazilian GMP (Good Manufacturing Practice Certificate) within two years can be considered a great success. Cosmetics and personal care products are currently not required to obtain the Brazilian Good Manufacturing Practice (aka GMP), and product classification is simpler.

Below is a summary table of classifications for each type of Health and cosmetic product:

| | |
|---------------------------------|--|
| Cosmetics and Cleaning supplies | Notification Class I and Registration Class II |
| Medical Devices | Notifications Class I and II |
| Medical Devices* | Registration Class I, II, III and IV * |
| Drugs * | New drug; similar; generic |
| Drugs * | Herbal medicines; energized; homeopathic Drugs |
| Drugs * | Simplified Notification (DRC 199/06) |

* Requirement of GMP



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- Identifying distributors in Brazil and/or Mexico and monitoring their performance.

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- Keep and host your records and licenses,
- Outsource your sales administration and financial management,
- Import, warehouse, label and distribute your goods in compliance with all federal, state and local authorities,
- Pre-Audit to obtain the Good Manufacturing Practice Certificate.

WHAT WE OFFER

- You remain independent and autonomous,
- You choose all local distributors freely,
- You can determine for yourself when and how you want to sell your products,
- We take care of your regulatory and administrative requirements,
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It is important to understand that the legislation on health is one of the most comprehensive in the world, hence the stringent requirements of ANVISA. These laws apply equally to Brazilian and foreign companies. It is also important to note that ANVISA is mandated to carry out its work by existing legislation and regulatory standards called DRC.

The main legal provisions are:

- Law No. 6.360/76
- Decree 74.094/97

Both devices process of medical devices in general,

The main RDC's are:

- RDC 56/2001 (central tenets of medical devices)
- RDC 59/2001 (requirements for registration of medical devices)
- RDC 25/2009 (regulating the CBPF)
- RDC 222/06 (regulates taxes paid at the time of submission of applications)
- RDC 16/04 (cosmetics)
- RDC 47/06 (cosmetics)
- RDC 162/09 (cosmetics)

Etc ...

This multiplicity of laws and regulations are constantly being changed or revised. The complexity of the laws can be understood only with the support of regulatory specialists, highly skilled professionals in the field of health and regulation. This holds true for both foreign and Brazilian companies, so with the proper tools a non-native business has the same opportunities as a local one to penetrate the growing Brazilian market.

There are really only three options:

1- Have your own local branch (creation, fusion/JV or acquisition): this approach involves the 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**, offer the following services:

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).

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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.

Other services:

As part of an expansion strategy, a company may wish to establish itself in Brazil, but not want to set up the infrastructure to handle day to day operations, transportation, billing, monitoring, etc. This is why some Brazilian companies, including MANDALA Service Provider, offer services tailored to the needs of the customer. First, a company entering the Brazilian market may decide to create a commercial office and outsource all other ancillary activities. MANDALA can help from the creation of the company in Brazil to all related proceedings (visa application, physical hosting, temporary financial monitoring and accounting). In addition to these services, Mandala can handle all operations from the importation of products to contracting distributors to the end customer:

This allows the foreign company to devote itself entirely to marketing its products. These solutions are obviously limited in time, but are extremely valuable because they allow the foreign company to devote itself entirely

to the marketing of its products and depending on the results, decide to gradually recover its related services. You can also opt to outsource your commercial structure, or even the management of the local subsidiary.

These offers are fully adaptable to the implementation strategy of the company, but are based on a simple concept: "Why do it yourself, when you can depend on someone else to do it right." The cost of these benefits is quickly offset by savings of time and energy gained by outsourcing many activities of a company. And this in a country that is extremely bureaucratic with multiple laws that overlap and at times conflict with each other, to the delight of law firms. For example, 2 million laws were created in Brazil in the last 20 years and most only serve to complicate the lives of Brazilian companies. The Brazilian government seeks by all possible means to control what happens on its territory and has a strict policy for its regulatory environment, building rules that are some of the most stringent in the world. Hence there exist a multiplicity of demands from organizations and taxation controls. For example, a ship arriving in a Brazilian port must provide no fewer than 112 documents from 14 different departments! A business, even without work must submit forms between four and 10 from organizations such as tax authorities, the local social security (INSS), the Federal Economic Fund, Bank of the State responsible for managing a fund for employees, and so on). For a foreign company unaccustomed to all of these constraints it can be quite discouraging. From the very beginning such a company must surround itself with expensive advisors (lawyers, accountants, etc). That is why the idea of subcontracting these responsibilities is very attractive.

Source:

MANDALA Brazil Represented by CroftHawk





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Canada's Medical Device Regulations compared to US and EU

Comparison

| Country | Classification | Quality system | Product registration | Regulator |
|---------|---|---|---|---|
| US | Class I, II, III By product codes for generic device types; CFR | 21 CFR 820 QSR; FDA inspects | Premarket submissions - 510(k), PMA cleared/ approved by FDA | FDA – CDRH (PMA, 510k); Office of Compliance - inspection |
| Canada | Class I, II, III, IV Risk based classification rules in Canadian Medical Devices Regulations -CMDR Class I, IIa, IIb, III | ISO 13485:2003 CMDCAS Certificate Class II to IV: full QS Audited by recognized third party-registrars | Class II to IV: Medical Device Licence Class I: MDEL (Medical Device Establishment Licence), not product specific | Health Canada's Medical Devices Bureau (product licences) Health Products and Food Branch Inspectorate (MDEL) |
| EU | Risk based classification Rules in Directives | ISO 13485:2003 certification by Notified Bodies - routes to conformity | CE Mark Notified Body (third party) Class II, III: Safety/effectiveness, Essential Requirements Class I most self declared (except sterile, measuring)IVDD- Common Technical Specifications | Competent Authorities per member state; variation in Directives implementation |

Source: Canreg

Regulatory updates

The Guidance Document “Medical Device Licence Renewal and Fees for the Right to Sell Licensed Medical Devices”, released on April 1, 2012, illustrates the steps involved in renewing a medical device licence issued by Health Canada for Class II, III and IV medical devices. It covers the application of Section 43 of the Medical Devices Regulations (MDR) and Division 3 of the Fee Regulations.

Highlights

- The license renewal process requires manufacturers of medical devices that are licensed for sale in Canada to inform Health Canada each year, before November 1, that the information submitted with their license application and any subsequent amendments has not changed.
- Manufacturers of licensed Class II, III and IV medical devices are charged an annual fee, payable at the time of license renewal, for the right to sell their devices in Canada.
- If the annual gross sale revenue (AGR) of the medical device (or the sale revenue of any medical devices in the same family) in Canada during the previous calendar year is less than \$20,000, the fee for the right to sell is \$50; in all other cases the fee is \$330.
- Manufacturers that have not completed their first calendar year of selling their medical device in Canada will have their fee deferred for the right to sell that device to the end of that year.
- The right to sell fee is to be increased annually by 2%, rounded up to the nearest dollar, beginning on April 1, 2012.

License Renewal Procedure

1. Early in August of each year, Health Canada sends each manufacturer (or its regulatory correspondent) who is marketing licensed Class II, III or IV medical devices in Canada an annual license renewal package. If the renewal package has not been received by September 1, the manufacturer or their regulatory correspondent should request the package to Health Canada. It is important that the manufacturer notify Health Canada if there is a change regarding the regulatory correspondent or contact information previously submitted. Failure to do so may result in the cancellation of a licence.

Note: All new licences issued between July 27 and November 1 will be automatically renewed and do not need to submit renewal forms, but renewal fee is still required although payment will be deferred. Manufacturers will be provided with a renewal advisory when their medical device license is mailed to them.

2. The completed renewal form must be returned to the Device Licensing Services Division of MDB before November 1 of the year it is received, together with completed Reduced Fee Request and Certification Forms if applicable, except where the fee is being deferred.

Note: No fee payment should accompany the return of the forms.

3. Renewal applications and any reduced fee requests are processed on receipt. Invoices, accompanied by a description of the medical device licenses renewed and the fees assessed, are mailed in February for payment within 30 days. The invoice documentation confirms renewal of the medical device license(s).

4. Failure to comply with the above provisions may result in cancellation of existing medical device licenses. The invoicing process will bill only valid renewed medical device licenses for which fee payment has not been deferred.

5. Medical device licences not renewed have either been discontinued by the manufacturer; or have been cancelled by MDB for failure to renew by the November 1 deadline. If a medical device licence has been cancelled, the product cannot be sold in Canada and the manufacturer (or regulatory correspondent) has to submit a new medical device license application with related fee payment.

Fees for the right to sell licensed medical devices

- The fees for the right to sell a licensed medical device are charged annually for the twelve month period beginning on November 1 of each year; according to the Annual Gross Revenue (AGR) from the sales of the medical device and any other devices in the same medical device family during the previous calendar year. The fee is \$50 if the AGR is less than \$20,000, \$330 if the AGR is \$20,000 or more.
- The right to sell fee is to be increased annually by 2%, rounded up to the nearest dollar; beginning April 1, 2012; i.e., in 2012, the standard fee will be \$337 and the reduced fee will be \$51.
- For annual adjustment, each year a Notice of Intent will be published in Canada Gazette, Part I setting out the revised fees. Additionally, Health Canada will review the costs associated with service delivery every three years and will propose new or amended fees to reflect the results of those reviews, if necessary.

Timing of Payment and Invoicing

- The fee is payable at the time the manufacturer provides Health Canada with the information referred to in subsection 43 (1) of the MDR.

However, manufacturers must wait for the invoice, sent in February, before submitting payments.

- In order to qualify for the reduced fee, the manufacturer must submit a completed Reduced Fee Request and Certification Form with their renewal, signed by the individual responsible for the manufacturer's financial affairs certifying that the AGR from the sales of the medical device for which a licence has been issued, along with any other devices in the same medical device family, is less than \$20,000.
- Health Canada may verify the AGR and if the statement provided by the manufacturer is inaccurate, it may be required to produce sales records, within 60 days, that have been audited by a qualified independent auditor; to determine the fee payable or the amount of the remission by Health Canada.
- Deferred Payments: if the manufacturer has not completed its first calendar year of selling a medical device, payment is deferred to the end of the first complete calendar year that the medical device is on the market. Manufacturers may accumulate AGR data from the sale of the new product to determine if they are eligible for the reduced fee. Request for a reduced fee in respect of the newly marketed device must be submitted no later than January 20 of the year following the first completed calendar year that the device was on the market, otherwise an invoice for the standard fee will be sent.

For further information: Medical Devices Bureau, Health Products and Food Branch
2934 Baseline Road, Tower B

Address Locator: 3403A Ottawa, Ontario K1A 0K9 Canada

Email: Info@hc-sc.gc.ca

Phone: +1 613 957 2991 - Toll free: 1 866 225 0709 Fax: +1 613 941 5366

Sources:

Canreg - www.canreginc.com

Health Canada - <http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php>



www.iae.it

IAE SpA
Head Office and Factory
Via Fabio Filzi, 53
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November 14-17, 2012
Germany

US Healthcare Reform on track?

On March 23rd, 2010, President Obama signed the Affordable Care Act to introduce a comprehensive health reform to be fully implemented by 2014. The ambitious goal is to make US health system more sustainable, reduce costs and improve efficiency while at the same time expanding coverage and improving quality of medical care.

Although now the reform is still in its early stage and its full development is going to require some years before the effects are evident, some progresses have already been made. The main provisions already implemented, or in course of implementation, are summarized below:

I. Medical insurance

Rate Review

One of the most significant provisions already implemented is the Rate Review program, enabling states to require insurance companies to justify their premium increases, in order to be eligible for \$250 million in new grants provided by the Affordable Care Act. Available through federal Fiscal Year 2014, these grants are helping states improve their review of proposed health insurance premium increases and hold insurance companies accountable for unreasonable premium increases. In fact, insurance companies who rise premiums above a reasonable and justifiable threshold may not be able to participate in the new Affordable Insurance Exchanges program in 2014. The program started on September 1, 2011 for most individual and small group plans. According to the 2012 Progress Report issued by the Department of Health and Human Services, as a result of scrutiny conducted by the states and the HHS, several states reported a decrease in the number of proposed rate increases that exceed 10%.

In particular:

- States' insurance rate increases reduced to an average 8 to 9%, well below the proposed increases.
- 27 states have reduced, or sometimes rejected, the rate increases that insurers have proposed and in the last three quarters, states reduced rates by, on average, 0.7%, 1.2%, and 4.5% respectively, with the last quarter representing state actions after the Rate Review program took effect.

Rate review has helped consumers be informed on proposed rate increases also by posting double-digit rate increases on the government website companyprofiles.healthcare.gov, almost 200 until March 2012. Each post provides an explanation from the insurer, and evaluation from the state or HHS as for its reasonableness.

Pre-existing Condition Insurance Plan

Temporary program serving as a bridge to 2014 to provide health coverage to individuals with pre-existing medical conditions who have been uninsured for at least six months.

States have the option of running this new program in their state. If a state has chosen not to do so, a plan has been established by the Department of Health and Human Services in that state. Enrollment into the federal plan began July 1, 2010; implementation dates for the state-operated plans vary.

Medical Loss Ratio (MLR)

The "medical loss ratio" refers to the amount of insurance premiums that an insurer spends on health care and activities that improve health care quality. Under the Affordable Care Act, at least

- 85% of all premium dollars collected by insurance companies for large employer plans

- 80% of all premium dollars for plans sold to individuals and small employers have to be spent on health care services and health care quality improvement rather than overhead and administrative costs.

From 2012, an insurer that does not spend enough on health care or quality-improving activities must give a rebate to people enrolled in the plan or the small business that purchased it.

In the course of 2012, insurers' medical loss ratios are due to be reported on companyprofiles.healthcare.gov

Adult Dependent Coverage to Age 26

Effective new plans and existing plans when they renew on or after September 23, 2010. Young adults are allowed to stay on their parent's plan until they turn 26 years old. (For group plans, it is valid unless the young adult is offered insurance at work.)

Consumer Protections in Insurance

On June 28, 2010, the Office of Consumer Information and Insurance Oversight (OCIO) issued regulations implementing several consumer protection provisions in the health reform law. Certain of the provisions take effect for new plans and existing plans when they renew on or after September 23, 2010, while other provisions only apply to new plans established on or after September 23, 2010.

Consumer protection provisions:

- Prohibit individual and group health plans from placing lifetime limits on essential benefits
- Prohibit rescinding coverage except in cases of fraud
- Prohibit denying children under 19 coverage based on pre-existing medical conditions



- Reduce annual limits on the dollar value of coverage are restricted, to be eliminated in 2014

Insurance Plan Appeals Process

Requires new health plans to implement standardized internal and external processes for consumers to appeal health plan decisions. On August 4, 2011, HHS released a list of states with approved external review processes through which consumers may appeal coverage determinations or claims to their insurance company.

Coverage of Preventive Benefits

All new plans must cover preventive services rated A or B by the U.S. Preventive Services Task Force, recommended immunizations, preventive care for infants, children, and adolescents, and additional preventive care and screenings such as mammograms and colonoscopies without charging a deductible, co-pay or coinsurance.

On August 1, 2011, HHS issued interim final regulations on preventive services, including requirements that insurers cover birth control with no cost-sharing. On August 3, 2011, HHS issued an amendment to the final regulations. On February 15, 2012, HHS issued an issue brief estimating that 54 million Americans had received preventive benefits without cost-sharing.

CO-OP Health Insurance Plans

Creates the Consumer Operated and Oriented Plan (CO-OP) to foster the creation of non-profit, member-run health insurance companies. On February 21, 2012, HHS announced that "seven non-profits offering coverage in eight states have been awarded \$638,677,300."

2. Medicare and Medicaid

Medicaid Coverage for Childless Adults and Community-Based Services

The Centers for Medicare and Medicaid Services have issued letters to State Health Officials and Medical Directors providing guidance on:

- new optional Medicaid coverage for childless adults with incomes up to 133% of the federal poverty level (States will be required to provide this coverage in 2014)
- new options to provide home and community-based services through Medicaid state plan amendment to certain individuals; states may also extend full Medicaid benefits to individuals receiving home and community-based services under a state plan.

Medicaid Health Homes and Chronic Disease Prevention

- Creates a new Medicaid state option to permit certain Medicaid enrollees to designate a provider as a health home and provides states taking up the option with 90% federal matching payments for two years for health home-related services.

- Provides 3-year grants to states to develop programs to provide Medicaid enrollees with incentives to participate in comprehensive health lifestyle programs and meet certain health behavior targets. On February 24, 2011, the Centers for Medicare and Medicaid Services announced the availability of \$100 million in grants for states to offer incentives to Medicaid beneficiaries who participate in prevention programs and demonstrate improvements in health risk and outcomes.

Accountable Care Organizations in Medicare

The new law provides incentives for physicians to join together to form "Accountable Care Organizations" to better coordinate patient care and improve the quality, help prevent disease and illness, and reduce unnecessary hospital admissions. If Accountable Care Organizations provide high quality care and reduce costs to the health care system, they can share in the cost savings they achieve for the Medicare program.

On December 19, 2011, CMS announced 32 health care organizations that will participate in the new Pioneer Accountable Care Organization project.

Changes in Medicare payments

- Reduces annual market basket updates for inpatient and outpatient hospital services, long-term care hospitals, inpatient rehabilitation facilities, and psychiatric hospitals and units and adjusts payments for productivity. Productivity adjustments are added to market basket update in 2012.
- Provides a 10% Medicare bonus payment for primary care services; also, provides a 10% Medicare bonus payment to general surgeons practicing in health professional shortage areas. Implementation from January 1, 2011 through December 31, 2015.
- Eliminates cost-sharing for Medicare-covered preventive services that are recommended (rated A or B) by the U.S. Preventive Services Task Force and authorizes Medicare coverage for a personalized prevention plan, including a comprehensive health risk assessment. As of October 6, 2011, 20.5 million people had participated in the free Annual Wellness Visit or received other preventive services with no cost-sharing.
- Freezes the income threshold for income-related Medicare Part B premiums for 2011 through 2019 at 2010 levels resulting in more people paying income-related premiums, and reduces the Medicare Part D premium subsidy for those with incomes above \$85,000/individual and \$170,000/couple.

3. Prevention and primary care

Prevention and Public Health Fund

Appropriates \$5 billion for fiscal years 2010 through 2014 and \$2 billion for each subsequent fiscal year to support prevention and public health programs.





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HHS has allocated \$500 million in funding for fiscal year 2010, half aimed to improve the supply of primary care providers and half to support public health and prevention priorities. On February 11, 2011, HHS announced \$750 million in funds from the Prevention and Public Health Fund to help prevent tobacco use, obesity, heart disease, stroke and cancer; and to increase immunizations.

Rebuilding the Primary Care Workforce

- Provides incentives to expand the number of primary care doctors, nurses and physician assistants, including funding for scholarships and loan repayments for primary care doctors and nurses working in underserved areas.
- Establishes the National Health Care Workforce Commission to coordinate federal workforce activities, make recommendations on workforce goals and policies and collect regional workforce data.
- Establishes Teaching Health Centers and provides payments for primary care residency programs in community-based ambulatory patient care centers.

4. Drug coverage

Medicaid Drug Rebate In Effect

Increases the Medicaid drug rebate percentage for brand name drugs to 23.1% and to 13% of average manufacturer price for non-innovator, multiple source drugs.
Extends the drug rebate to Medicaid managed care plans.

Closing the Medicare Drug Coverage Gap

Seniors who reach the coverage gap received a 50% discount when buying Medicare Part D covered brand-name prescription drugs. Over the next ten years, additional savings on brand-name and generic drugs will be added until the coverage gap is closed in 2020.

As of August 4, 2011, 900,000 Medicare beneficiaries who hit the prescription drug doughnut hole received a 50% discount on their prescription drugs.

5. Taxation

Changes to Tax-Free Savings Accounts

- Excludes the costs for over-the-counter drugs not prescribed by a doctor from being reimbursed through a Health Reimbursement Account or health Flexible Spending Account and from being reimbursed on a tax-free basis through a Health Savings Account or Archer Medical Savings Account.
- Increases the tax on distributions from a health savings account or an Archer MSA that are not used for qualified medical expenses to 20% of the amount used.

Tax on Medical Devices

Imposes an excise tax of 2.3% on the sale of any taxable medical device after December 31, 2012.

On February 7, 2012, the IRS issued a proposed rule providing guidance on the tax that will be imposed on medical devices.

Annual Fees on the Pharmaceutical Industry

Imposes new annual fees on the pharmaceutical manufacturing sector. On August 15, 2011, the Internal Revenue Service issued temporary regulations that provide guidance on the annual fee imposed on pharmaceutical companies.

Sources:

US Department of Health & Human Services - www.hhs.gov

Kaiser Family Foundation - www.kff.org

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| TI Ref No: | 10310758 | Document Type: | Procurement Forecast |
|-------------------------|--|----------------|----------------------|
| Description: | Procurement Forecast for Supply of medical equipment, instruments and furniture specifically for ambulatory facilities Mures County Hospital | Deadline: | 29 Dec 2012 |
| Country: | Romania | Bidding Type: | Global (ICB) |
| TI Ref No: | 10302669 | Document Type: | Procurement Forecast |
| Description: | Procurement forecast for Supply of needles for anesthesia | Deadline: | 30 Dec 2012 |
| Country: | Croatia | Bidding Type: | Global (ICB) |
| TI Ref No: | 10134164 | Document Type: | Procurement Forecast |
| Description: | Procurement forecast for MFV: Anesthesia- and intensive products part I | Deadline: | 05 Dec 2012 |
| Country: | Norway | Bidding Type: | Global (ICB) |
| | 10043118 | Document Type: | Procurement Forecast |
| Description: | Procurement forecast for Framework agreements surgical instruments | Deadline: | 22 Nov 2012 |
| Country: | Norway | Bidding Type: | Global (ICB) |
| TI Ref No: | 9670979 | Document Type: | Tender Notice |
| Description: | Tenders are invited for Dental Chairs | Deadline: | 01 Nov 2012 |
| Country: | United States | Bidding Type: | Global (ICB) |
| TI Ref No: | 9660590 | Document Type: | Tender Notice |
| Description: | Tenders are invited for Supply of 1 unit wheelstretcher; etc for the use of ftfmh, mdh, avdh, adh & ipho of this province. | Deadline: | 19 Oct 2012 |
| Estimated Project Cost: | PHP 1.158435 Million | | |
| Country: | Philippines | Bidding Type: | Global (ICB) |
| TI Ref No: | 9181401 | Document Type: | Procurement Forecast |
| Description: | Procurement Forecast for Surgical Gloves | Deadline: | 22 Jul 2012 |
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| TI Ref No: | 9156259 | Document Type: | Procurement Forecast |
|--------------|--|----------------|----------------------|
| Description: | General Procurement Notice for Supply of Laboratory Equipment and Consumables to the Project \Involving and Integrating Animal Health Services in the Livestock Value Chain through Public Private Dialogue in Ethiopia (LVC-PPD)\ in Ethiopia | Deadline: | 20 Jul 2012 |
| Financier: | European Union (EU), | | |
| Country: | Ethiopia | Bidding Type: | Global (ICB) |
| TI Ref No: | 8902967 | Document Type: | Procurement Forecast |
| Description: | Procurement forecast for Endoscopic Supplies | Deadline: | 14 Jun 2012 |
| Country: | Norway | Bidding Type: | Global (ICB) |
| TI Ref No: | 10385420 | Document Type: | Tender Notice |
| Description: | Tenders are invited for Procurement of ECG | Deadline: | 21 Dec 2012 |
| Country: | China | Bidding Type: | Global (ICB) |
| TI Ref No: | 10121836 | Document Type: | Tender Notice |
| Description: | Tenders are invited for Supply of Surgical Tools | Deadline: | 20 Dec 2012 |
| Country: | Saudi Arabia | Bidding Type: | Global (ICB) |
| TI Ref No: | 8859294 | Document Type: | Prequalification |
| Description: | Invitation for Pre Qualification for Supply of Medical Equipment. | Deadline: | 17 Jun 2012 |
| Country: | Kenya | Bidding Type: | Global (ICB) |



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RetisMed - Developing Medical Innovations

RetisMed is a networking among several companies of the medical equipment sector, supported by CNA Emilia Romagna (National Confederation of Small Businesses and Craft Firms, Health & Well-being and Manufacturing sectors).

The aim of RetisMed is to enhance the development potentialities of the medical equipment sector companies of the territory, by supplying data on the sector; services and business advisors on markets, innovation and research. The member companies will have the opportunity to relate to the public research and to connect their own processes with those of the university and health systems, in order to create innovation, through the contribution that Senaf and the Universities of Bologna, Ferrara and Verona can offer to the network activities.



Different assumptions led to conceive this totally innovative idea that grow up in Emilia Romagna Region:

1. The Italian medical equipment sector represents 5,8% of the total of the health expenditure and is the 3rd market in Europe; it is mainly formed by small sized companies, primarily located in Central-Northern Italy.

2. The medical equipment market is marked by a total lack of actors and agencies able to supply information and data on the sector as far as market, innovation and research are concerned.

3. The shortage of information, of guidelines on medical equipments allows to gather only partial and generic data. For the companies, it is difficult to find specific information on the single sections of the medical equipment sector at national, European and International level.

RetisMed, medical network for innovation, aims at filling in these gaps by acting as a dynamic Observatory for market, innovation and research in the sector of medical equipment, but also as a service network for administrative and technical fulfillments, for the internationalization, for activating support services for the company's activity.

RetisMed partecipated in MEDICA 2011 (Dusseldorf-Germany) the most important trade medical equipment fair sector with a institutional

stand in which five companies presented their products and services. RetisMed is oriented to create new opportunity market for all companies, in particular is interested at private and public hospital, health and medical center, as supplier for medical equipment industries.

Actually RetisMed is composed by 8 Italian companies:

1. **ARTE ORTOPEDICA srl:** orthopaedic prosthesis production
www.arteortopedica.com;

2. **CORAZZA srl:** production of leather and cork insoles
www.corazzagroup.com;

3. **EURTRONIK STUDIOERRE srl:** medical equipment design and production
www.eurtronik.it

4. **POLIAMBULATORIO CENTRO ROMEA srl:** health center

5. **C.O.d.E.R. consortium** composed by 42 Emilia Romagna Region companies to commercialize disable equipment

6. **MINELLI UTENSILI srl:** Production of tools and mechanical engineering machining products for biomedical sector
www.minelliutensili.it

7. **SILFRADENT srl:** equipment for medical line and dental laboratories
www.silfradent.com

8. **SPAZIO SENZA LIMITI srl:** solution for reduced mobility to help displacements within domestic environments
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RetisMed is going to take part to MEDICA 2012, visit our stand!



Silfradent: From blood to tissue regeneration

CGF stands out among new discoveries, it is a platelet concentrate isolated from blood samples through a process implemented by SILFRADENT-Italy

Over the last 10 years, the tissue engineering made enormous progress in identifying new strategies in tissue regeneration field, such as the use of "platelet concentrate" which constitutes a relevant and innovative clinical approach.



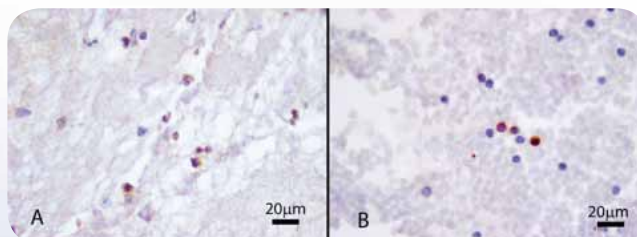
Several studies have highlighted the importance of platelets for tissue regeneration thanks to their ability to provide a large quantity of growth factors: Pdgf (Platelet derived growth factor), Tgf- β (Transforming growth factor- β), Fgf (Fibroblast growth factor), Vegf (Vascular endothelial growth factor) and Igf (Insulin-like growth factor) are involved in the induction of cell proliferation, in the remodeling of the extracellular matrix and in the angiogenic mechanisms, which are implemented during the different stages of regeneration.

In light of these considerations, in recent years several methods to produce platelet concentrates that contain a high concentration of autologous growth factors have developed. Platelet concentrates are obtained from patient's venous blood through a standardized process of centrifugation, which (sometimes with the addition of exogenous substances) allows to isolate a fraction rich in platelets and growth factors, precisely known as "platelet concentrate" or "platelet gel". Concerning the clinical application, the regenerative effect of these preparations is widely demonstrated in different clinical fields such as Maxillofacial

Surgery, Orthopedic Surgery, Aesthetic Surgery, Ophthalmology, Sports Medicine and Dermatology.

CGF (Concentrated Growth Factors) represents a new generation of platelet concentrates able to hold inside a higher concentration of autologous growth factors. Like other platelet concentrates, it is isolated from blood samples through a simple and standardized separation protocol, which is performed by means of a specific centrifuge (Medifuge MF200, Silfradent srl, Forlì, Italy) without the addition of exogenous substances. Its main feature is in its consistency: it is an organic matrix more rich in fibrin and therefore more dense than other platelet concentrates able to trap a greater quantity of platelets and growth factors. Furthermore, it has been found to contain CD34 positive cells, cellular elements which are normally recruited by blood to damaged tissues and which play a key role in maintaining vascular homeostasis and in angiogenesis and neovascularization.

Concerning CGF applications, its efficacy has been so far demonstrated in oral and maxillofacial surgery, in maxillary sinus lift procedure and profile ridge augmentation. However, its features make it suitable for its use (alone or with other biomaterials) in other fields where tissue regeneration is required.





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Salud Mesoamerica 2015 Initiative

The Mesoamerican region consists of the seven countries of Central America, Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama, as well as the nine south-eastern states of Mexico.

In spite of progress in health over the past decade, many services do not reach the bottom 20% of the population in the region. The Mesoamerican region has several efforts towards economic and social integration which have been implemented in two phases: the Puebla-Panama Plan, established in 2001, and the Mesoamerica Integration and Development Project (Proyecto Mesoamérica) started in 2008.

The Salud Mesoamérica 2015 Initiative is a **public/private partnership** aiming at reducing health coverage and quality gap for the **poorest 20% of the Mesoamerican population**, that is 8 million people living in poverty, and especially for women and children under five years of age, by supporting local governments' efforts to reach the health Millennium Development Goals.



The Initiative has been created for a five-year period and concludes in 2015.

The long-term goal is to create political and financial commitment to formulate pro-poor health policies and contribute to the eradication of malaria and control of dengue, by increasing the supply, quality and use of basic health services in poor communities.

Participants to the initiative are the Bill & Melinda Gates Foundation, the Carlos Slim Health Institute (ICSS) and the Government of Spain and the Inter-American Development Bank (IDB), that are each contributing US\$50 million to implement health solutions mainly designed for poor children and women in the region through projects in the areas of:

- reproductive health
- maternal, neonatal and child health
- maternal and child nutrition
- immunization
- malaria and dengue

The IDB is the implementing agency, responsible for designing projects jointly with countries' health ministries, who in turn will allocate matching funds. The Initiative also includes support for information system improvements and human resource strengthening within health systems.

Intervention Areas:

Nutrition

Chronic malnutrition and anemia result in delayed growth that challenges particularly rural and/or indigenous populations. Two intervention packages are proposed with a focus on areas where there is a high prevalence of stunting, micronutrient deficiencies, food insecurity and poverty. **A third plan is provided for less affected areas:**

1. The first intervention package supports consumption through Conditional Cash Transfers (CCTs) and provision of complementary fortified foods.
2. The second package includes provision of complementary fortified foods and micronutrients.

All interventions include education on breastfeeding, hygiene and immunization, and appropriate complementary feeding practices, vitamin A, zinc, and prenatal supplements.

Immunizations

Timely vaccination of children between 12 and 24 months of age in the poorest 20% of the population continues to be a significant challenge. Only 57% of children are fully vaccinated in a timely manner in Mesoamerica, and by country, the population ranges between 85% in Belize and Honduras and 54% in El Salvador and Guatemala.

The inclusion of new vaccines in national immunization schedules faces regulatory barriers and a lack of high-level agencies responsible for immunization policies in the Mesoamerican countries.

To broaden coverage and strengthen immunization systems, actions proposed are:

1. Develop projects that allow knowledge gaps to be filled in the area of increasing coverage in hard to reach areas.
2. Strengthen immunization policies.
3. Implement evidence based best practices (such as integrating vaccination with other health-related services), which may be used for decision making.

Maternal child health / Reproductive health

There have been considerable improvements in the basic indicators in maternal, child, and reproductive health in the Mesoamerican region in the past ten years. However, the maternal mortality rates in the region have remained among the highest on the continent due to limited access to safe childbirth and emergency obstetric care, suitable handling of the complications associated with pregnancy and abortion, and contraceptive services for the poorest 20%.

Neonatal mortality is related to the limited, difficult access to services and qualified professionals providing prenatal and postnatal care.

Interventions are planned in the following areas:

1. Implementation of quality basic service in obstetric emergencies and interventions related to infections, eclampsia, hemorrhages, and miscarriages, as well as community training in these aspects.
2. Basic services for newborns, especially those who are underweight at birth and/or have health complications.
3. Providing at least six methods of family planning, as well as advisement and training in the implementation of the latest contraceptive methods for both men and women.

Nicaragua

The Salud Mesoamérica 2015 Initiative signed the first operation with the Government of El Salvador. The Minister of Finance of this Central American country, Mr. Carlos Caceres, and the IDB Chief of Operations in the country, Mr. Gabriel Castillo, ratified the commitment that will start the activities of the Initiative in Mesoamerica. SM2015 operation in Nicaragua will contribute to the reduction of maternal, neonatal and child morbidity and mortality through a strategy of comprehensive health-care to improve access, utilization and quality of maternal and reproductive health services, and neonatal and child care in the poorest areas of the country.

The operation has three components:

- extension of health coverage for women of childbearing-age and maternal and child health;
- development of basic infrastructure;
- improvement of logistics and local information systems.

The total cost is US\$6,933,897; of which US\$4,622,599 will come from the SM2015 grant, and US\$2,311,298 from the country's own funds. If the agreed targets are met, at the end of the scheduled 18 months for execution, the Initiative will award the government an additional US\$1,155,650 to spend in the health sector.

Belize

In February, acting Prime Minister of Belize and IDB President signed an agreement for a \$1.25 million operation, the SM2015 Initiative's first project in Belize that aims to reduce maternal and infant mortality among the poor; benefiting more than 30,000 young women and children.

Over the past few years, Belize has made great strides towards the Millennium Development Goals, but health gaps persist, especially in the poorest areas. Preventable conditions associated with infectious

diseases and lack of access to, or use of health services disproportionately affect women of reproductive age and children, limiting their human development potential. These inequities can contribute to the perpetuation of the cycle of poverty. In 2006, a full 33% of children under five were malnourished among the poorest one-fifth of the population, compared with 18% at the national level. This first SM2015 operation in the country seeks to contribute to the reduction of maternal, infant and child mortality in the poorest districts of the country.

The Ministry of Health of Belize and the SM2015 Initiative each pledged US\$500,000 for the first 18 months of the program. If the Ministry of Health meets certain agreed upon goals, SM2015 will reimburse half of the Ministry's original investment (US\$250,000) for further spending on other health-related purposes. The first of three planned operations expects to reach more than 30,000 poor young women and children between 0 and 5 years old through quality improvement of maternal, neonatal, child and reproductive health services and strengthening community based platforms to increase coverage.

Belize has been a leader in the region for Performance Based Financing, especially through its work in the National Health Insurance (NHI) and existing National Level Performance Frameworks. "Belize has made important progress in providing health services to its people, and indicators such as life expectancy and infant mortality have improved dramatically in recent years", said Belize's Minister of Health during the signature event, "but these gains have yet to reach the most marginalized populations, with parts of Belize lagging behind others, so now, the Salud Mesoamerica 2015 Initiative and the IDB will work with Belize in close coordination to succeed in having a real impact in vulnerable communities".

Source: www.sm2015.org

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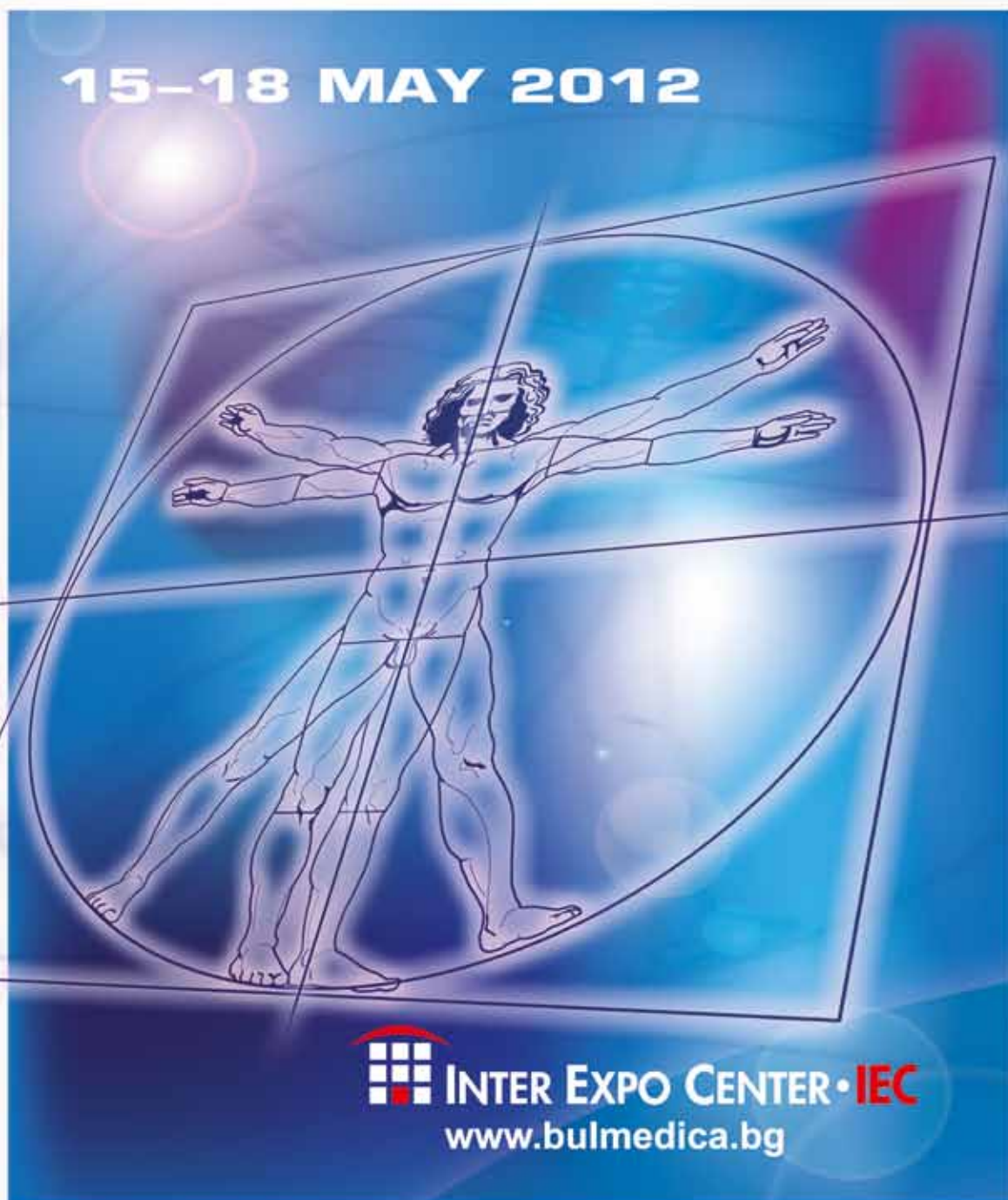
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Two years after earthquake, little victories for children in Haiti recovery

UNICEF released a report showing that two years after the earthquake that devastated parts of Haiti, the situation for children in the country is slowly improving, though critical challenges remain.

According to the report, there is clear evidence of healing and progress for children, particularly in the areas of education, health, nutrition and child protection.

UNICEF has helped more than 750,000 children to return to school and some 80,000 of them are now attending classes in 193 safe, earthquake-resistant schools constructed by the organization. Over 120,000 children enjoy structured play in one of the 520 child friendly spaces. More than 15,000 malnourished children have received life-saving care in 314 therapeutic feeding programmes supported by UNICEF. And 95 rural communities have launched new programmes to improve sanitation.



In the area of child protection, a major step has been that the government of Haiti has strengthened its legal framework for institutionalized children. Prior to the earthquake the government did not know how many children were living in institutions - or even where they were. Now, with UNICEF's support, the first ever Directory of Residential Care Facilities has been launched; so far more than half of the country's 650 centres have been assessed; and over 13,400 children (out of an estimated 50,000 living in residential care) have been registered. The government has also signed the Hague Convention on Inter-Country Adoption, which protects the rights of children, birth parents, and adoptive parents by establishing minimum standards for adoptions. "There is evidence of little victories everywhere, although serious gaps and inadequacies in Haiti's basic governance structures remain," said Françoise Gruloos-Ackermans, UNICEF's representative in Haiti.

"Make no mistake: the country remains a fragile state, beset by chronic poverty and under-development. Its weak institutions leave children vulnerable to shocks and the impact of disaster"

The report notes that with 4,316,000 children under 18, most of them still only have limited opportunities for survival, development and protection. Although they begin 2012 with a long-awaited new government and national budget, children are affected by the various challenges which remain for a country where the scars of disaster are still visible on the infrastructure, institutions and social systems. More than 500,000 individuals still shelter in over 800 different displacement sites across the earthquake-affected area. Some 77 per cent were renters before the earthquake, meaning most have no homes to return to. An outbreak of cholera in the earthquake's wake continues to place an additional burden on already severely limited infrastructure and services.

"The country will need strong and steadfast support to overcome the challenges it still faces," said Gruloos-Ackermans. "While the death toll and destruction from the earthquake were unmatched in modern times, the resources mobilised in the wake of disaster were also exceptional," she added. "Together they present a 'once a lifetime' opportunity to set Haiti on a course that arrests and reverses decades of degradation and mismanagement."

UNICEF, in the last year of its "transitional programme" for earthquake recovery, continues to implement a mix of humanitarian relief, capacity development for institutional re-building and advocacy simultaneously, in order to address both acute and chronic challenges that prevent the realisation of child rights. However, funding gaps still remain.

UNICEF is appealing for US \$24 million for immediate humanitarian needs in 2012 to support vulnerable children through five key projects in health, nutrition, water and sanitation, education, and child protection. Another US \$30 million is needed for longer term development assistance.

UNICEF says keeping children safe, healthy and learning is a mutual goal - one shared by parents, teachers, both public and private sector entities, religious organisations, the new government and others across the nation. A wide range of partners are working together to innovate, problem-solve and generate momentum to lead to a sustainable future for the children of Haiti.

Source: www.unicef.org

About UNICEF

UNICEF works in more than 190 countries and territories to help children survive and thrive, from early childhood through adolescence. The world's largest provider of vaccines for developing countries, UNICEF supports child health and nutrition, good water and sanitation, quality basic education for all boys and girls, and the protection of children from violence, exploitation, and AIDS. UNICEF is funded entirely by the voluntary contributions of individuals, businesses, foundations and governments.

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Venue: Roma Fairground

Infomedix booth: Pav.5- F04



• 07-09/05/2012 **HKTDC - Hong Kong International Medical Device and Supplies Fair 2012**

(Hong Kong)
Organiser: Hong Kong Trade Development Council
Unit 13, Expo Galleria Hong Kong Convention and Exhibition Centre
Wan Chai, Hong Kong
Tel: +852 1830 668 - Fax: +852 2824 0026
E-mail: exhibitions@hktdc.org
Website: www.hktdc.com/globalnetwork
Venue: Hall 3F, Hong Kong Convention and Exhibition Centre

• 09-11/05/2012 **Africa Health 2012** (Johannesburg - South Africa)

Organiser: Informa Exhibitions Healthcare Division
PO Box 28943, Dubai - UAE
Tel: +971 4 3365161 - Fax: +971 4 3364021
E-mail: africahealth@informa.com
Website: www.africahealthexhibition.com
Venue: Johannesburg Expo Centre, Nasrec, South Africa

Infomedix booth: 7C10



Sao Paulo

• 15-18/05/2012 **BULMEDICA/ BULDENTAL 2012**

(Sofia - Bulgaria)
Organiser: BULGARREKLAMA AGENCY
Fax: +359 2 9655 231
Website: www.iec.bg // www.bulmedica.bg
Project Manager BULMEDICA:
Maria Jeliaskova
Tel: +359 2 9655 277
E-mail: mjeliaskova@iec.bg
Venue: Inter Expo Center

Infomedix booth: 4D12



• 16-18/05/2012 **KIHE 2012**

(Almaty - Kazakhstan)
Organiser: GiMA GmbH (part of ITE Group PLC)
Ms. Cornelia Limbach
healthcare@gima.de
Organiser's contact information:
www.healthcare-events.com
Venue: Atakent Exhibition Center, Almaty

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• 22-25/05/2012 **HOSPITALAR**

2012 (Sao Paulo – Brazil)

Organiser:

HOSPITALAR Feiras e Congressos

Padre Joao Manuel, 923, 6th floor

01411-001 -Sao Paulo, Brazil

International Trade Manager: Katherine Shibata

E-mail: internacional@hospitalar.com.br

Tel: +55 11 3897 6199

Fax: +55 11 3897 6191

Website Hospitalar: www.hospitalar.com

Venue: Expo Centre Norte, Sao Paulo, Brazil

Infomedix booth: White Hall 119



• 23-25/05/2012 **MedSib 2012 - 23rd International Specialized Medical Exhibition**

(Novosibirsk – Russia)

Organiser: GIMA GmbH (part of ITE Group PLC)

Ms. Cornelia Limbach

healthcare@gima.de

Organiser's contact information:

www.healthcare-events.com

Venue: Novosibirsk Expo Centre

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June

• 30/05-01/06/2012 **Medima 2012- 11th International Specialized Medical Exhibition**

(Krasnodar – Russia)

Organiser: GiMA GmbH

(part of ITE Group PLC)

Ms. Cornelia Limbach

healthcare@gima.de

Organiser's contact information:

[http://www.healthcare-events.com/pages/](http://www.healthcare-events.com/pages/contact_us.html)

[contact_us.html](http://www.healthcare-events.com/pages/contact_us.html)

Venue: KrasnodarExpo

• 14-17/06/2012 **Taiwan Health 2012**

(Taipei – Taiwan)

Organiser: Taiwan External Trade

Development Council (TAITRA)

5-7 Fl., 333 Keelung Rd., Section 1

Taipei 11012, TAIWAN

Tel. +886 2 725 5200

E-mail: tiec@taitra.org.tw

Website: www.taiwantrade.com.tw

Venue: Taiwan World Trade Center (TWTC)

July

• 15-18/07/2012 **IRAN HEALTH 2012** (Tehran – Iran)

Organiser: Expotim International Fair

Organisation, Inc.

Fulya Mah. Vefa Deresi Sok. No 9

34394 Sisli - Istanbul - Turkey

Tel: +90 212 356 00 56

Fax: +90 212 356 00 96

E-mail: info@expotim.com

Venue: Tehran Permanent Fair Ground

August

• 08-10/08/2012 **FIME 2012**

(Miami Beach-Florida – USA)

Organiser: FIME International

Medical Exposition, Inc.

3348 Seventeenth Street

Sarasota, FL 34235 USA

Tel: +1 941 366 2554

Fax: +1 941 366 9861

Venue: Miami Beach Convention Center

Infomedix booth: I 177



• 22-25/08/2012 **VIETNAM MEDI-PHARM 2012**

(Ho Chi Minh City – Vietnam)

Organiser: VINEXAD

9 Dinh Le, Hoan Kiem District, Hanoi, Vietnam

Project Manager: Ms Nguyen Minh Chau

Tel: +844 38255546 ext. 434

Fax: +844 39363085

Mobile: +84 90 4811648

E-mail: minhchauvinexad@gmail.com

chaunguyen.vinexad@gmail.com

Website: www.vinexad.com

Venue: Tan Binh International Exhibition & Convention Center

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- **Managing Director:** Baldo Pipitone
baldo.pipitone@infodent.com
- **Publisher:** Riccardo Chiarapini
riccardo@chiarapini.it
- **Assistant Manager:** Paola Uvini
paola@infomedix.it
- **Editor & Exhibition Manager :** Lara Pippucci
lara@infomedix.it
- **Advertising-Foreign Markets:** Riccardo Sirio Bonati
riccardo.bonati@infomedix.it
- **Advertising-Italian Market:** Daniela Fioravanti
daniela@infomedix.it
- **Web Advertising & Database:** Michela Adinolfi
michela@infomedix.it
- **Art Director:** Karlen Zamora Zúñiga
karlen@infodent.com
- **Customer & Accounting Dept.:** Nadia Coletta
nadia@infodent.com



www.infomedix.it - info@infomedix.it

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Via Vicenza 14 Int. 8
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Tel: +39 0761 352 198 - Fax: +39 0761 352 133

September

• 05-07/09/2012 Astana Zdorovie 2012- 9th Healthcare International Exhibition

(Astana – Kazakhstan)

Organiser: GiMA GmbH (part of ITE Group PLC)

Ms. Cornelia Limbach

healthcare@gima.de

Organiser's contact information:

www.healthcare-events.com

• 12-14/09/2012 MEDICAL FAIR ASIA (Singapore)

Organiser: Messe Duesseldorf Asia Pte Ltd

3 HarbourFront Place

#09-02 HarbourFront Tower Two

Singapore 099254

Tel: +65 6332 9620

Fax: +65 6332 9655 // 6337 4633

E-mail: *medicalfair-asia@mda.com.sg*

Website: *www.medicalfair-asia.com*

Venue: Suntec Singapore, Hall 601 – 603



INFOMEDIX

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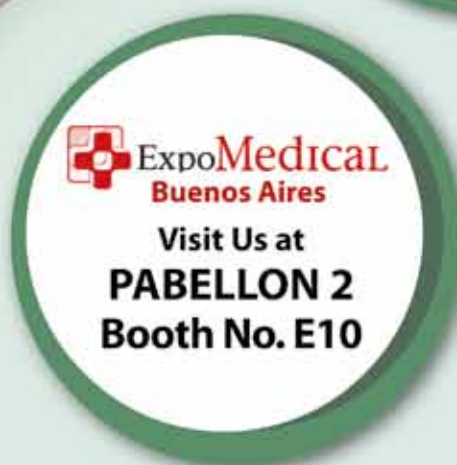
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