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1 /2012

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January / April issue

ARAB HEALTH

www.infomedix.it

### **INNOVATIVE** ENDOSCOPY COMPONENTS, LLC Quality endoscopes, parts & equipment



Autoclavable HD Compatible Endoscopes, Camera Systems, Light Sources Etc., Made in Germany

Endoscopios Autoclave, Compatible con HD, Sistemas de Cámaras, Fuentes de luz, etc., Fabricados en Alemania

Endoscópios autoclave, Compatível con HD, Sistemas de Câmeras, Fontes de luz, Etc. Fabricado na Alemanha

Eberle Shaver System and Shaver Blades, Made in Germany Sistema de Shaver Eberle y las Cuchilla, Fabricado en Almania Sistema de Shaver Eberle e Lâminas, Feito em Alemanha

Worldwide Largest Inventory of New and Pre-Owned Endoscope **Repair Parts** 

Más Grande Inventario Mundial de Piezas de Repuesto nuevos y usados para endoscopio

Maior Estoque Mundial de Peças de Reposição, Endoscópio Novos e usados

### CCD-Chip Repair, Sales of CCD's and Parts

Reparación de Camera (CCD-Chip), Las Ventas de Camera (CCD's) y las Piezas

Conserto de Câmera (Chip-CCD), as Vendas de Câmera (CCD's) e as Peças



Multilingual Repair Training and Consulting Formación de Reparación Multilingüe y Consultoría Multilingual Formação de Reparação e de Consultoria



### Focus on Vietnam

"Despite positive international judgements of Vietnam's performance, a series of recent scandals and the impact of the economic crisis have uncovered some serious problems that undermine the country's ability to maintain its position as a model of development, also making its future prospects, which had so far seemed rosy, less easy to predict than expected..."

18



### Outlook on North & South Korea

"South Korea has one of Asia's largest economies while North Korea is one of the most isolated and poor countries in the world. They are two sides of the same coin as the division of Korea in 1945 created two opposite countries from one single nation..."





### Healthcare in French Polynesia

"The World Bank categorizes French Polynesia as a high income country. The WHO calculates that 10% of GDP is spent on healthcare. The majority of population has access to quality health care in medical and dental facilities, pharmacies, private clinics and a large government hospital in Tahiti..." N T E R N A T I O N A L CONNECTING MEDICAL BUSINESS WORLDWIDE Middle East & Asia Issue

### Contents

### HIGHLIGHTS

**4-9** Learn more about our Advertiser's Products...

### EXHIBITION PRE & POST SHOW REPORTS

- II MEDTRADE
- II MEDIPHARM VIETNAM
- I2 REHABTECH ASIA
- I2 BULMEDICA
- I4 MEDEXPO
- I4 ECR

### FOCUS

18-29 Focus on the Medical Market in Vietnam

## INTERNATIONAL MARKET & TRENDS

31-39 Outlook on North & South Korea

40-43 Healthcare in French Polynesia

### **CERTIFICATES & REGULATIONS**

**44-47** Initial Registration of Import Products in China

40-43



### Headache Disorders

"Headache disorders are among the most common disorders of the nervous system. Headache is a painful and disabling feature of a small number of primary headache disorders namely migraine, tension-type headache, and cluster headache..."

16-17



### Asia & Pacific Regional Economic Outlook

"Growth in the Asia-Pacific region has slowed. External headwinds played a major role, as the recovery in advanced economies suffered setbacks. Weaker momentum in China and India also weighed on regional economies. For Asia as a whole, GDP growth fell to its lowest rate since the 2008 global financial crisis during the first half of 2012..."

49-55

#### Cover page

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

AmicoX-rayTechnologies44	Led Spa
Applied Optical Technologies P. Ltd43	Maltron I
Axel Srl	Medica S
Biegler GmbH45	Mexpo In
BMI Biomedical International Srl	Operon S
Calze G.T. S.r.l	OXAIR Ltd
Conf Plastic Srl	Pastelli Sı
Ekom Spol s r.o55	Rexmed I
Euroclinic Srl	Silfraden
H. Buschkuhl GmbH54	Sterylab S
IAE Spa	Superma
IMD Generators Srl	Tinget - P
Innovative Endoscopy Components, LLC	VillaSiste
Inside Front Cover	YSYMedia

### HOT TOPIC

- 16-17 Headache Disorders
- **49-55** Asia & Pacific Regional Economic Outlook

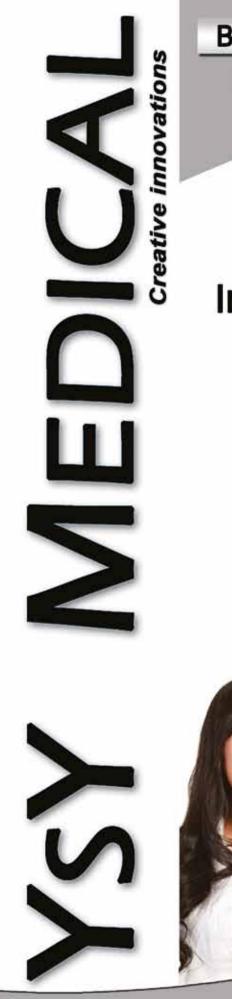
### **PRESS RELEASE**

59 Silfradent: CGF-Concentrate growth factor from tissue regeneration

### 56 BUSINESS ANNOUNCEMENTS

### 60-63 EXHIBITION & CONGRESS CALENDAR

### 64 WHAT'S NEXT



### **BIOFEEDBACK**) ELECTROTHERAPY

### Visit us at Arab Health **ZQ50**

## Imagine the future...



YSY MEDICAL - ZAC Pôle Actif - 9, Avenue de la Fontanisse - 30660 GALLARGUES LE MONTUEUX (FRANCE) Tel: +33 4 66 64 05 11 - Fax: +33 4 66 29 11 43 - Email: export@ysy-medical.fr - Website: www.ysy-medical.fr

### Stainless Steel Binds Us..... We Grant Hygiene



··· Highlights

Since 50 years we manufacture conveyance and stocking systems made of aluminum and stainless steel that help to serve internal logistic of hospitals structures, internal industrial laundries handling or the confidential paper shredding business. After several years serving biggest industrial laundries in the world, we are concentrating more and more in stainless steel equipments and furniture where we are able to realize "ad hoc" (customized) solutions for surgical theatres, CSSD (Central Sterile Supply Department) like stocking cupboards, surgical sinks, pass-through

cupboards, stools and technical logistic trolleys. Our products are carefully studied and design granting total hygiene, with no cutting edges and interstice in order to prevent bacteriological proliferation; always pointing on a perfect functionality and great handiness. For any further information feel free to get in contact with us.

info@confindustries.it / www.confindustries.it

### Sanlyleg - The quality policy



"Ongoing commitment to providing our customers with the products developed for them, according to their specifications with efficiency and dynamism, at the appointed time and in the best way, having identified their needs with skill and care. Thanks to our advanced technology, to a constant research of new yarns, and our

know-how, working in areas where our expertise and our human resources allow us to excel, our first objective is to provide the best products at competitive prices.

We promote the development of skills and expertise of our staff, through innovation, training and involving individuals, in a spirit of mutual growth and interest. In this growth we also involve our suppliers.

We comply to the highest standards in terms of individual safety, as well as for our protection, as example of warranty

and reliability for our customers. The continuous development of our skills, the steady improvement of our organization, the satisfaction of our customers are the main features that distinguish our daily work." Alberto Ghelfi

www.sanyleg.com /info@sanyleg.com

### **Endoscopy Components, LLC- valuable products** and services in over 40 countries worldwide



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 repair parts for Flexible and Rigid Endoscopes are our Specialty. Please contact us if you need CCD-Chip Repair or to purchase a CCD-Chip. Multilingual Repair Training and Consulting services are also offered at our Facility in Fort Lauderdale, Florida. Innovative Endoscopy Components, LLC 733 Shotgun Road, Fort Lauderdale, FL 33326, USA Tel: 001 954 217 8780- Fax: 001 954 217-8781 www.IECendoscopy.com.



### EKOM medical line: AIR FOR LIFE .....



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. www.ekom.sk / ekom@ekom.sk





### Tinget: Bringing the sterilization process to another level



**STE-16/18/23D** Is a class "B" autoclave according to the European standard EN 13060, and works in the method of fractionated pre-vacuum. As the air is evacuated from the chamber with a very effective and quite vacuum pump, all instruments like solid, wrapped hollow instruments or textiles get optimal result of the sterilization.

- LCD graphic display.
- I 6liters, I 8liters, 23litersIndependent steam generator

- Italy Water pump and valvesOverhead type water tank
- Sterilization temperature: 121 and 134°
- Fully automatic cycles: 7 sterilization cycles and 3 test programs.
- Each cycle with fractionated post vacuum for effective drying
- 3 buttons, very easy to use, any people can run it easily.
- With pressure protection locking system
- Documentation: Printer interface and USB function. (Printer is optional)
- The sterilization and drying time can be adjusted

www.tingetclave.com / info@tingetclave.com

### **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. Operon's products are mainly used for human clinical diagnosis, gastrointestinal infections, celiac disease, tumor markers, inherited diseases, infectious diseases.

There are five technological lines:

- Raw materials: monoclonal antibodies and recombinant antigens
- Immunochromatographic rapid tests ELISA plates (LisaKIT)
- Molecular diagnostic tests
- Custom Services

In OPERON new projects are proposed continuously and we work closely with Research Centers and Public Private www.operon.es / sales@operon.es Visit us at ARAB HEALTH (section MEDLAB)

### Amico Mammography Unit



Full-field digital mammography unit MAMMO-RPd improve detection of breast cancer and improve the comfort of patients undergoing a mammogram. Improved diagnosis and detection ultimately improves the prognosis for many with breast disease leading to a reduction in mortality:

- Compact and ergonomic system design
- Motorized C-arm height and rotation adjustment
   Large investigation area
- Touch-screen interface at assistant workstation
  Large investigation area
  Indication of breast compression force, compressed thickness and projection angle
- Greatest image resolution

www.amico.ru/en / export@amico.ru

### Your strategic and reliable partner



IAE is a major role player in the international x-ray market as the only independent manufacturer in Europe of rotating anode tubes. With its wide product line of more than 100 insert/housing combinations, IAE is a strategic and reliable partner to the most important equipment manufacturers globally. A recently developed product is a **Rotating anode X-Ray equipment film and digital detectors**. Compact design with miniature high voltage connectors. A single piece, extruded aluminium structure ensures an enhanced temperature uniformity and a good heat dissipation in natural or forced convection conditions.











28-31 JAN 2013 DUBAI INTERNATIONAL CONVENTION AND EXHIBITION CENTRE

Look out for the 200 NEW exhibitors in the Plaza Hall









WHERE THE HEALTHCARE WORLD COMES TO DO BUSINESS

### **Electrostimulation Needles PlexAx**



The **Electrostimulation Needles PlexAx**, with innovative materials and system of assembly, offer to the anesthetist the ideal device to perform anesthesia correctly and allow the precise identification of the area to anesthetize, while reducing the risk of neuro-lesions, the drug dosage, and permitting also its routine employment for infiltrative techniques of analgesic therapy.

### Its use may be applied for single injection or continuous block:

Single Injection - After the correct identification of the target nerve, the anesthetic is administered through the dedicated infusion way following a modality of advancing that considers both the resistance perceived by the operator and the administration rate that should not be more than ImI every 3 seconds.

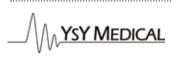
**Continuous Peripheral Blocks** - Through the introduction of a catheter into the perinervous space, allows repetitive or continuous infusions of an esthetics and analgesics: this promotes a better and a less painful postoperative recovery and a more rapid rehabilitation. www.axel-med.com / info@axel-med.com **Visit us at ARAB HEALTH 2013 – SAH48** 

### Whole Body Photon Therapy System Bionic 880



H. Buschkühl GmbH, located in Germany, is the manufacturer of the Whole Body Photon Therapy System Bionic 880. The system stimulates cells and harmonizes hormons. This offers a wide range of treatment possibilities ie. Psychosomatic illnesses, Psychosomatic illnesses, Somatic disturbances, Vegetative dysfunctions, Chronic illnesses, Burn-Out-Syndrome, Healing of wounds, Burning, Ulcus cruris, Addiction and Smoking withdraw, Depression, Hyperactivity, Regulation of weight. For its concept to treat Bacteria disease w/o using antibiotics the company received the German industrial Award. *Visit us at ARAB HEALTH 2013 Stand S3E50 ARABIAN Ethicals.* www.buschkuehlgmbh.com / www.biophoton.de / info@biophoton.de

### **Rehabilitation: Biofeedback & Electrotherapy**



YSY MEDICAL is a French manufacturer specialized in rehabilitation by electrotherapy and biofeedback, EMG muscular evaluation and assessment since 1996.

We offer a new range of products with innovative features: undisturbated EMG biofeedback signal, true real time biofeedback (without latency), high EMG sampling allowing accurate unparalleled acquisition, flowmetry, measurement of skin resistance, effective and very com-

fortable stimulation. All treatment protocols (500) are designed in partnership with leading international trainers. Software is complete, ludic, powerful and very easy to use.

Applications for therapy: urogynaecology, men urology, proctology, sport, traumatology, rheumatology, hemiplegia, vascular, aesthetics... Devices come in two ranges: stand-alone and computerized systems.

Certifications: ISO 9001:2008, ISO 13485:2003, CE mark

export@ysy-medical.fr / www.ysy-medical.fr

### **BIEGLER - Medical Devices for over 35 years**



BIEGLER GmbH develops and manufactures medical devices and disposables for over 35 years. The company recently introduced AUTOPRESS, a device working directly with Biegler blood and infusion warmers to deliver blood and fluids at high flow rates or as a stand-alone unit to deliver fluids at constant pressure up to 300 mmHg wherever needed. When connected to an electrical outlet, Biegler

Pressure Infusor automatically maintains pressure on blood and IV fluid bags. Pressure range is zero to 300 mmHg. **Features at a glance:** 

- Pressure is adjustable and always maintained
- Precise pressure setting from zero to 300 mmHg with electronic control
- Accomodated pressure cuffs 2 × 500 or 2 × 1000 cc
- Fits on any IV pole and rail
- Mains operated
- Small and lightweight
   Pressure cuffs can be
- Pressure cuffs can be emptied rapidly and easily
- Significant reduction of set up time CE marked www.biegler.com / office@biegler.com Visit us at Arab Health: S3F50







··· Highlights



### Some innovations in BMI's world



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

- 9" or 12" I.I. tubes for a wider investigational area
- IK × IK digital imaging system, providing higher definition with lower x-ray dose
- X-ray monoblocs with stationary or rotating anode tubes
- Outstanding free space and depth for improved patient's accessibility and easier operations
- USB socket for pen recording and LAN socket for DICOM connection
- Digital memories for storage of 3.000/6.000/100.000/800.000 images according to the selected configuration
- Angio version featuring 30 fps acquisition rate, DSA, powerful image processing and large storage capacity

www.bmibiomedical.it / info@biomedical.it

### Relaxsan socks for diabetics and sensitive feet



Thanks to their manufacturing characteristics and the properties of the yarns are recommended for diabetics' feet and for those people who suffer from sensitive and delicate feet, arthritis and athlete's foot. RelaxSan Diabetic Socks are manufactured with special yarn as Cotton & Crabyon and Cotton & X-Static. Besides it is available a TOE SOCKS model that main characteristics are 100% seam-free interiors to avoid

abrasion or irritation to skin and toes, prevents friction between toes and help to prevent toe conflicts, made with natural cotton fiber that ensures an-allergic effects and silver thread that have many therapeutic and antibacterial properties (especially maintain bacteria free zone between toes). Socks are knitted without elastic, so it will not bind or hinder circulation. Diabetic Toe Socks is recognized by the "Italian Ministry of Health." www.relaxsan.it / info@relaxsan.it



### Laboratory Equipment exported in more than 150 countries

### **I**REXMED



REXMED Industries Co., Ltd. was established in 1976 as a professional manufacturer and exporter of medical and laboratory equipments in Taiwan. Nowadays, we are specialize in Operating Theatre, Delivery Room, Dental Clinic, ENT Clinic, ICU / CCU, Veterinary Clinic, Laboratory Room, Central Sterile Supply Department Turnkey Project Solutions Medical Equipment: suction unit, autoclave sterilizer, operating table, ophthalmic table, delivery table, veterinary table, stretcher, hospital bed, operating lamp, ENT treatment unit, ENT / ophthalmic 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 magnetic stirrer, vortex mixer, roller mixer and centrifuge. Our products have popular used in domestic hundred of hospitals, medical schools, dental and scientific clients and export to more than 150 countries around the world. Furthermore, we were selected by European firms as reliable company to supply our products for WHO, World Bank, UN and NGO's projects. Projects reference http://www.rexmed.com/news/project www.rexmed.com / sales@rexmed.com

### **MULTICORE**® is the latest disposable biopsy device entirely designed and manufactured by STERYLAB



MULTICORE® provides an optimised needle visualization under ultrasound guided biopsy procedures. By the natural of its constituent material it functions at any angle of entry into the body in relationship to the generation of sound waves by the ultrasound transducer. Thanks to its perfect smoothness, avoids any risk of seeding of malignant cells along the needle's path from the patient's body out. Specimens provided through MULTICORE® are particularly abundant and allow a quick,

safe and easy biopsy procedure, either performed manually or through the most common imaging guiding systems, such as CT, US. MRI.

www.sterylab.it / info@sterylab.it

### LEUKOCYTE ADSORBER LA25 The new column for Therapeutic Leukocyte Apheresis

LA25 LEUKOCYTE ADSORBER is a new therapeutic tool in the MEDICA S.p.A. LA25 LEURUCT LE ADSUMDER is a new merapeutic toor in the hands of the physicians in order to treat complex Autoimmune Diseases like Ulcerative Colitis, Crohn disese, Rheumatoid Arthritis and others. It is designed to carry out Therapeutic Leucocyte Apheresis.

Developed by MEDICA Spa, it shows cutting-edge features:

- Selective Removal of Leukocyte and Platelets involved in the inflammatory process
- Excellent Biocompatibility because of its MEDISULFONE® , hydrophilic membrane
- Very Low Priming volume: 120 ml
- It is supplied in a ready-to-use disposable kit containing also the lines and accessories

The therapeutic protocol consists of one session per week repeated for 5 weeks. The clinical trial

demonstrated a significant reduction of the inflammatory Indexes (MAYO score, CDAI, IBDO). It comes with a dedicated pump for blood circulation named LEUKOSMART fitted with a blood pump and a smaller pump for Heparin infusion.

www.menfis.it / sales@menfis.it Visit us at Arab Health: Hall SAEED Booth Number SAD75

### I.M.D. GENERATORS & P.S.M.

I.M.D. GENERATORS merged with P.S.M. company, becoming then a unique big monoblocs and generators company. I.M.D. proposes itself as an ideal partner for the production of radiological assemblies of medical units or industrial control systems, putting at disposal of its partners its expertise in the industrialization of systems, their interfacing and certification. The aim of this specific offer of cooperation is to optimize the implementation of

each component into the system, and to improve the power performance according to the partner's needs for a specific typology of application.

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

### Villa Sistemi Medicali: the right partner to complete your medical imaging world

Since 1958, Villa Sistemi Medicali designs, manufactures and markets radiological systems organized in the following product families:

- Analog and digital R/F systems
- Analog and digital general radiographic rooms
  - Mobile Units
- Surgical X-ray units
- Mammography
- Dental panoramic, intraoral and 3D

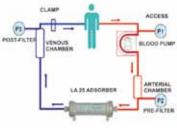
The grouping of these product families in dental and medical lines is a key feature that has

allowed Villa Sistemi Medicali to assert itself in the international market of diagnostic radiology devices. Customers' expectations and needs are the inspiring concepts for the design of radiological systems, while is a commitment forwards Patients the

transmission of values such as experience, diagnostic quality and reliability, deeply rooted in all Villa's products. The precious cooperation with over 150 dealers makes Villa's presence and product distribution possible in over 90 countries worldwide. www.villasm.com / marketing@villasm.com Visit us at Arab Health 2013 Stand S2F80 Hall Sheikh Saeed Hall 2

# Highlights







Under the Patronage of H. H. Sheikh Hamdan Bin Rashid Al Maktoum Deputy Ruler of Dubai, Minister of Finance President of the Dubai Health Authority

# Bubai Derma Skin Health is Our Concern 2013

### Dubai World Dermatology and Laser Conference & Exhibition Dubai International Convention & Exhibition Centre

Mark your Calendar **NOW!** 16-18 April 2013 **CONNECT** with **5000+** Dermatologists, Laser Specialists and Aesthetic Surgeons

SOURCE cutting edge products from 500+ brands

**GET AHEAD** of the competition in the booming skin care and aesthetic laser market

**LEARN** from over **88** world-renowned speakers

EARN more than 50 CME points





### Discover the Latest On!

Aesthetic Medicine • Anti-Aging • Best Practices For 2013 • Body Contouring • Cosmetic Dermatology Dermatological Therapies & Surgeries • Dermatology Science • Dermatopathology Facial Rejuvenation Techniques • Hair And Nail Disorders • Dermatopharmacotherapy Medical Dermatology & Research • Lasers • Liposuction • Pediatric Dermatology Plastic Surgery For The Dermatologist • Psychodermatology



INDEX® Conferences & Exhibitions Organisation Est.

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### www.dubaiderma.com

### Medtrade, the international trade event for the home healthcare industry

Medtrade, the international trade event for the home healthcare industry, was staged again in Atlanta last October and attracted some 600 exhibitors and thousands of business professionals from all 50 U.S. states and an additional 50 countries around the world. Medtrade is the only truly business-to-business exhibition that focuses on the entire range of home medical and healthcare products and solutions.

### Markets and products represented at Medtrade include:

- durable medical equipment mobility products respiratory products
  - sleep products
- rehab products
- diabetic supplies
- bathroom safety equipment bed/mattress & accessories
- aids to daily living disposables

**MEDTRADE 2012** 

- incontinence/ostomy
- orthotics/prosthetics and many more...
- business services

No other event showcases more innovative products for the home healthcare industry, and provides unmatched opportunities to discover some of the hottest products, latest industry trends and newest merchandising techniques!

### Medtrade's attendee profile includes:

- home medical equipment providers
- pharmacy-based home medical equipment retailers • distributors
- home health agencies
- rehab/nursing facilities • manufacturer sales reps
- mass retail with home medical equipment

In the specter of an ageing population in many countries around the world, home healthcare solutions become more and more vital. Product innovation and improvements in home medical and care equipment are continuing to enable the growing elderly population and people with chronic illnesses and disabilities to remain living independently in their own homes, Medtrade is the event where you find those new products that will keep your business at the forefront of the home healthcare market in your country or region and that will give you an advantage over your competitors.

In addition to the exhibition, Medtrade also features an extensive conference program featuring over 120 sessions with practical and down-to-earth business seminars and presentations on topics such as:

• business operations

• legislative & regulatory

- sales/marketing
- customer service
- staff development • rehab & assistive technology • respiratory care
- retail
- and more...

Next year's Medtrade is scheduled for 8-10 October 2013 in Orlando, Florida. Before that, there will also be the Medtrade Spring show in Las Vegas, Nevada on 20-21 March 2013, and Medtrade Asia in Hong Kong on 27-29 August 2013. For more information, go to www.medtrade.com, or contact Frederic Lievens at the Medtrade European Office in Belgium at medtrade@skynet.be.

Don't stay behind in the growing home healthcare market. Make plans now to attend the Medtrade 2013 events!



### VIFTNAM MEDI-PHARM FXPO 2013 IN HOCHIMINH CITY

The 13th Vietnam International Hospital, Medical and Pharmaceutical Exhibition in Hochiminh City - VIETNAM MEDI-PHARM EXPO 2013

IN HCMC will be held from 22 - 24 Aug., 2013 at Tan Binh Exhibition & Convention Centre (TBECC), 446 Hoang Van Thu Str., Tan Binh Dist., Hochiminh City, Vietnam.

### There are 5 concurrent events:

MEDICA VIETNAM 2013: Vietnam International Exhibition on Medical & Laboratory Equipments

PHARMA VIETNAM 2013: Vietnam International Exhibition on Pharmaceutical Products and Processing, Packaging Machinery HOSPITA VIETNAM 2013: Vietnam International Exhibition on Hospital and Equipments

**OPTICA VIETNAM 2013:** Vietnam International Exhibition on Ophthalmology

DENTALVIETNAM 2013: Vietnam International Exhibition on Dental Materials and Equipments

This is the annual exhibition of Vietnam healthcare industry hosted by Ministry of Health of Vietnam and Ministry of Industry & Trade of Vietnam. Last year. VIETNAM MEDI-PHARM EXPO 2012 IN HOCHIMINH CITY welcomed more than 300 exhibitors from 20 countries and regions such as: Australia, France, Germany, Italy, Belarus, Russia, Japan, Korea, Malaysia, Singapore,

Thailan, China, Taiwan, Hongkong, India, Pakistan, Bangladesh, Vietnam... with exhibit ranges: Medical and laboratory products; pharmaceutical and processing, packaging machinery; healthcare and beauty; ophthalmological and dental products....

VIETNAM MEDI-PHARM EXPO 2013 in Hochiminh City will be an ideal platform for Enterprises to introduce their products and services in the most efficient way. This is also a golden opportunity for exhibitors to interchange, exchange experiences, seek for counter-parts, join ventures, signing contracts....

During the exhibition, there will be Conference introducing Vietnam medical & pharmaceutical market, trading policies when doing business in Vietnam hosted by related Departments, Associations of Ministry of Health of Vietnam.

For more information please visit www.medipharmexpo.com

MEDI-PHARM 201

- wound care products • in-home diagnostics
- lifts/hoists

### RehabTech Asia 2013

**RehabTech Asia** comes at a time where the requirements from the Asian disabled community are growing, and the population is ageing in tandem with Asia's economic progress and rapid urbanisation. To be held from 27 February to I March 2013 at Singapore EXPO Convention & Exhibition Centre, **RehabTech Asia** is set to be the preeminent trade exhibition on assistive technology, integrated care and rehabilitation engineering in Asia.

Jointly organised by Fiera Milano and Singex Exhibition Ventures Pte Ltd, the exhibition will be a dynamic marketplace for 100 exhibitors from the world over to showcase assistive devices, communication aids, mobility solutions, and rehabilitation robotics, to 4,000 serious buyers, academics, government officials, clinicians, and end-users from around Asia.

**RehabTech Asia** incorporates the Fundamentals Course in Assistive Technology by the Rehabilitation and Assistive Technology of North America, which is being conducted in Singapore for the first time by prominent American occupational therapist Ms Jill Sparacio and rehabilitation engineer Mr Jerry

Weisman. **RehabTech Asia** is also held in conjunction with the 2nd Singapore Rehabilitation Conference and 1st Asia Pacific NeuroRehabilitation Symposium.

Featuring renowned speakers such as Professor Dr Gert Kwakkel (Netherlands), Professor Li Jian An (China), Professor Dr Andreas Luft (Switzerland), Professor Dr Robert Riener (Switzerland), and Professor Robert Teasell (Canada), the Conference and Symposium will allow delegates to discover the latest treatment methods and technology applications, as well as learn the best practices for rehabilitating patients.

Supported by Singapore Manufacturing Federation and Singapore Exhibition and Convention Bureau, RehabTech Asia counts Singapore's Centre for Enabled Living, Ministry of Health Holdings, Ministry of Social & Family Development, SPRING Singapore, and Tan Tock Seng Hospital and its Centre for Advanced Rehabilitation Therapeutics as Strategic Partners.

With such strong government and industry support, **RehabTech Asia** will certainly give delegates ample opportunities for meaningful discussions to maximise the health and well-being of people with disabilities, care requirements and chronic conditions through technology.

### www.rehabtechasia.com

### The International Forum For Innovative Technologies For Medicine



### BULMEDICA BULDENTAL

The upcoming 47th edition of the international specialized exhibition **BULMEDICA / BULDENTAL** will be held from 15th to 17th of May, 2013 at Inter Expo Center-Sofia.

It is one of the most prestigious Southeast European events in the field of medical care and is traditionally held under the auspices of the Ministry of Health of the Republic of Bulgaria. The event is supported by the Bulgarian Medical Association and the Bulgarian Dental Association.

The exhibition halls will expose new models of clinical laboratory and diagnostic devices, medical machinery and dental equipment, tools, reagents, consumables and other medical treatment products, as well as best practices in global health care to support experts working in hospitals, medical diagnostic and consulting centers, medical and dental clinics.

**BULMEDICA** will again demonstrate new equipment and devices for therapeutic services, innovative systems and apparatus for higher precision in diagnostics, laboratory equipment and supplies for individual medical practices, emergency care, preventive care, orthopedics and rehabilitation, auxiliary devices with various clinical utilization, etc.

**BULDENTAL** will present, in the sectors of dentistry and dental prosthetics, the latest equipment, devices and instruments for dental, medical, and denture cabinets, beauty parlours and denture laboratories, dental and denture materials and supplies, equipment for X-ray and dental offices, oral hygiene products, etc.

In the course of its long-standing history **BULMEDICA** / **BULDENTAL** has always enjoyed great interest from both Bulgarian and foreign participants. **BULMEDICA** / **BULDENTAL** in 2012 exposed products by 212 direct exhibitors representing 976 companies from 45 countries. Along with the traditional participants, we had 54 new participants from Bulgaria, Romania, Greece, Hungary, Poland, Germany, South Korea, Russia, France, China, Slovenia, Turkey and other countries.

As usual, medical and dental companies from South Korea retain the level of activity, organizing their national participation at a common booth. There will be organized again a collective representation of companies from the Italian health sector, in cooperation

with the Agency for foreign promotion and internationalization of Italian enterprises (ICE). The 2012 exhibition registered 12 000 visits by health experts which is a good indication for the solid interest towards the event. The profile of **BULMEDICA / BULDENTAL** has already been recognized as a forum for contacts and business initiatives of professional organizations and a wide range of health care specialists and experts. Just as any other year, the organizers of the 2013 edition have provided discussions, demonstrations, corporate presentations and seminars on topical issues for the medical community.

The exhibition does its best to keep in pace with the latest trends, increasingly focusing on both the standard of services provided by health specialists and the comfort of the patients, their safe and high quality health care. Next year, the official journal of **BULMEDICA / BULDENTAL** – the worldfamous today business guide initiated by Dental Tribune Bulgaria and Bulgarreklama Agency, will again timely brief health experts on the novelties and highlights of the exhibition program.

More information at: www.bulmedica.bg

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### **MEDXPO 2013**

A new international medical exhibition and congress, **MEDXPO 2013**, opens in London from 7th to 9th March 2013. This is a "must-visit" event for everyone involved in the medicine and healthcare sectors. Taking place at London's Alexandra Palace the event will provide a focus of collaboration for medical and healthcare professionals, specialists and academia. Never before has a medical conference and trade show brought together such a diverse range of people and organisations, dedicated towards advancing the medical and healthcare sector.

MEDXPO 2013 offers a dynamic meeting place that will attract all of those across the medical and healthcare industries, academia, and those concerned with Government policy. All who are invested in maintaining and growing R&D in the life sciences industry, and delivering benefits for patients around the world, should be there. Notable specialists and globally recognised speakers will address a programme of conferences and workshops, providing an opportunity for open discussion and debate about advances in healthcare, medicine

and surgical procedures.

The programme of speakers and workshops offers a platform to exchange views on the very latest global challenges in a converging world. Speakers and workshops will include:

- Dr Richard Smith (Fertility Preservation & Restoration)
- Dr Anba Soopramanien (Telemedicine)
- Steve Trim: (VenomTech Cancer Cells)
- Dr Mohamed Rela (Liver Transplantation)
- •Les Plant (UKTI Southeast)
- •Dr Kegang Wu (Link To China)

#### For the latest update please visit www.medxpo.co.uk.



This is an exceptional opportunity for visitors to initiate and enhance their relationships with medical and hospital equipment manufacturers and service providers, within a valued and respected meeting place. For healthcare industry suppliers, MEDXPO 2013 provides the ultimate in showcase exhibition space for the best of their products and

services, positioning themselves at the forefront of their field. Exhibitors are invited to sponsor **MEDXPO 2013** through a number of promotional packages. More information is available at www.medxpo.co.uk.

The attention of the entire medical community will be drawn towards this event as the world converges at Alexandra Palace, London from 7th to 9th March.

To see where healthcare is headed tomorrow, be a part of MEDXPO 2013.

### ECR 2013 is just around the corner

The European Congress of Radiology (ECR), the annual meeting of the European Society of Radiology (ESR) and the largest radiological meeting in Europe, will take place at the Austria Center Vienna from March 7-11, 2013. The ECR is the event where specialists, from all over the world and many different disciplines can come together and take advantage of a unique opportunity to meet with others in their field.

**ECR 201** 

The congress is constantly evolving, and the Programme Committee, as well as the ESR, strives tirelessly to stay ahead of the educational needs and demands of radiologists and radiographers. The ESR tries to imagine the future and invest in it. The 'Rising Stars' programme is aimed at attracting future specialists to the radiological sciences and over the years it has invited more than 3,000 students and young colleagues to take part in the ECR free of charge.

ECR 2013 will offer three Categorical Courses; 'Never without Arteries', 'Urogenital Imaging' and 'Oncologic Imaging: Follow-up of Systemic and Local Therapies'. These courses will provide participants with the most up-to-date information and knowledge.

Complex liver tumours require a multidisciplinary approach from several specialties. The ECR 2013 programme includes three sessions, presented by colleagues from both diagnostic and interventional radiology, that will show how experts from different disciplines, within the same institution, interact and decide on the best way to approach specific clinical situations.

In 2013, the successful 'European Excellence in Education – E3' will include fourteen 90-minute sessions, with attractive titles such as 'tips and tricks' and 'pitfalls'. The Foundation Course will deal with neuroimaging and will be followed by a self-assessment test. There will be two practical courses on how to 'Update your Skills', which will provide interactive demonstrations and opportunities for hands-on experience on 'How to biopsy' and 'How to ablate.'

Once again, the ESR has invited three countries and one partner discipline to share their expertise through the 'ESR Meets' programme. Chile, South Africa, Spain and the European-African Hepato-Pancreato-Biliary Association will present their most recent scientific developments in joint sessions and try to strengthen links between professionals. For the first time, the ECR will include a new session entitled 'EFRS meets' (European Federation of Radiographers Society) and this year they will be meeting Spain.

Participants will also have the opportunity to attend Refresher Courses and State-of-the-Art Symposia, learn more about the most recent New Horizons in radiology, or concentrate on Special Focus Sessions that cover a wide variety of topics.

### Registration and information at www.myESR.org/ECR2013

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# Headache disorders

### **Key Facts**

• Headache disorders are among the most common disorders of the nervous system.

• It has been estimated that 47% of the adult population have headache at least once within last year in general.

• Headache disorders are associated with personal and societal burdens of pain, disability, damaged quality of life and financial cost.

• A minority of people with headache disorders worldwide are diagnosed appropriately by a health-care provider.

• Headache has been underestimated, under-recognized and under-treated throughout the world.

Headache disorders are among the most common disorders of the nervous system. Headache is a painful and disabling feature of a small number of primary headache disorders namely migraine, tension-type headache, and

cluster headache. Headache can also be caused by or occur secondarily to a long list of other conditions, for example medication overuse headache.

### How common are headache disorders?

Globally, it has been estimated that prevalence among adults of current headache disorder (symptomatic at least once within the last year) is 47%. Half to three quarters of the adults aged 18–65 years in the world have had headache in the last year and among those individuals, more than 10% have reported migraine. Headache on 15 or more days every month affects 1.7–4% of the world's adult population. Despite regional variations, headache disorders are a worldwide problem, affecting people of all ages, races, income levels and geographical areas.

### What is the burden due to headache disorders?

Not only is headache painful, but also disabling. In the Global Burden of Disease Study, updated in 2004, migraine on its own was found to account for 1.3% of years lost due to disability (YLD).

Headache disorders impose a recognizable burden on sufferers including sometimes substantial personal suffering, impaired quality of life and financial cost. Repeated headache attacks, and often the constant fear of the next one, damage family life, social life and employment. The long-term effort of coping with a chronic headache disorder may also predispose the individual to other illnesses. For example, depression is three times more common in people with migraine or severe headaches than in healthy individuals.

### **Types of headache disorders**

Migraine, tension-type headache and medication-overuse headache are of public health importance as they are responsible for high population levels of disability and ill-health.

### Migraine

- A primary headache disorder.
- Most often begins at puberty and most affects those aged between 35 and 45 years.

• It is caused by the activation of a mechanism deep in the brain that leads to release of pain-producing inflammatory substances around the nerves and blood vessels of the head.

• Migraine is recurrent, often life-long, and characterized by attacks.

- Attacks include features such as:
- » headache of moderate or severe intensity;
- » nausea (the most characteristic);
- » one-sided and/or pulsating quality;
- » aggravated by routine physical activity;
- » with duration of hours to 2-3 days;

» attack frequency is anywhere between once a year and once a week; and

» in children, attacks tend to be of shorter duration and abdominal symptoms more prominent.

### Tension-type headache (TTH)

### • TTH is the most common primary headache disorder.

- Episodic TTH is reported by more than 70% of some populations; chronic TTH affects I-3% of adults.
- $\bullet$  TTH often begins during the teenage years, affecting three women to every two men.
- Its mechanism may be stress-related or associated with musculoskeletal problems in the neck.
- Episodic TTH attacks usually last a few hours, but can persist for several days.
- Chronic TTH can be unremitting and is much more disabling than episodic TTH.
- This headache is described as pressure or tightness, like a band around the head, sometimes spreading into or from the neck.

### Cluster Headache (CH)

- A primary headache disorder.
- CH is relatively uncommon affecting fewer than I in 1000 adults, affecting six men to each woman.
- Most people developing CH are in their 20s or older.
- It is characterized by frequent recurring, brief but extremely severe headache associated with pain around the eye with tearing and redness, the nose runs or is blocked on the affected side and the eyelid may droop.
- CH has episodic and chronic forms.

# ··· Hot Topic

### Medication-overuse headache (MOH)

• MOH is caused by chronic and excessive use of medication to treat headache.

- MOH is the most common secondary headaches.
- It may affect up to 5% of some populations, women more than men.
- MOH is oppressive, persistent and often at its worst on awakening.

### Social and economic burden of headache

Headache disorders are a public-health concern given the large amount of associated disability and financial costs to society. As headache disorders are most troublesome in the productive years (late teens to 50s), estimates of their financial cost to society – principally from lost working hours and reduced productivity – are massive.

In the United Kingdom, for example, some 25 million working- or school-days are lost every year because of migraine alone; this financial cost is matched by TTH and chronic daily headache combined. Headache is high among causes of consulting medical practitioners as onethird of all neurological consultations were for headache, in one survey. Yet, many of those troubled by headache do not receive effective care. For example, in the United States of America and the United Kingdom, only half of those identified with migraine had seen a doctor for headache-related reasons in the previous 12 months, and only two-thirds had been correctly diagnosed. Most were solely reliant on over-thecounter medications.

### Treatment

Appropriate treatment of headache disorders requires professional training of health professionals, accurate diagnosis and recognition of the condition, appropriate treatment with cost-effective medications, simple lifestyle modifications, and patient education. The main classes of drugs to treat headache disorders include: analgesics, anti-emetics, anti-migraine medications, and prophylactic medications. However a large number of people with headache disorders are not diagnosed and treated.

### Barriers to effective care

Lack of knowledge among health-care providers is the principal clinical barrier. Worldwide, on average only four hours of undergraduate medical education are dedicated to instruction on headache disorders. The minority of individuals with headache disorders worldwide are professionally diagnosed; 40% for those with migraine and TTH, while for MOH it is only 10%.

Poor awareness extends to the general public. Headache disorders are not perceived by the public as serious since they are mostly episodic, do not cause death, and are not contagious. The low consultation rates in developed countries may indicate that many sufferers are unaware that effective treatments exist. 50% of people with headache are estimated to be self-treating.

Many governments, seeking to constrain health-care costs, do not acknowledge the substantial burden of headache on society. They might not recognize that the direct costs of treating headache are small in comparison with the huge indirect-cost savings that might be made (eg, by reducing lost working days) if resources were allocated to treat headache disorders appropriately.

### WHO response

These evident burdens call for action. WHO recognizes this, and is a partner, with the non-governmental organization Lifting The Burden, in the Global Campaign against Headache. This initiative, began in 2004 and aims not only to raise awareness of headache disorders, but also, to improve the quality of headache care and access to it worldwide. WHO published the Atlas of headache disorders in 2011 describing the burden due to headache disorders and resources available to reduce them.

Source: WHO- www.who.int

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# Focus on The Medical Market in Vietnam

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### Economy

ietnam is composed of **63** provinces and five centrallygoverned cities (Hanoi, Ho Chi Minh City, Can Tho, Da Nang and Hai Phong). Provinces and cities are further grouped into eight main regions: Southeast, Red River Delta, Mekong River Delta, Northeast, Northwest, North Central Coast, South Central Coast, Central Highlands. About **70% of Vietnamese** people live in rural areas, and the majority works in the informal sector.

Since 1986 the Vietnamese centrally planned economy has gradually shifted towards a **socialist-oriented market economy** with a series of political and economic reforms known as "Doi Moi". The World Bank describes Vietnam as a "development success story", highlighting how the country, once one of the poorest countries in the world, has become a **lower middle income country** within a quarter of a century. During the last fifteen years, **average GDP growth has accelerated to over 7% per annum**.

GDP per capita has risen from US\$289 in 1995 to US\$1,168 in 2010 and GDP still growing at about 4.7% despite the global crisis, as the government adopted measures to curb rising prices and stabilize the currency (Vietnam dong). Roughly in the same period, the poverty ratio has fallen from 58% to 14.5% and most indicators of welfare have improved as well, allowing Vietnam to reach five of its ten original Millennium Development Goal targets. The OECD forecasts an average GDP growth of 6.3% per annum for the next four years.

The Government has made large scale investments to modernize the country's industrial and transportation infrastructure. 60% of the population still works in the agricultural sector, allowing the country's self-sufficiency and providing an important source of exports. However, industry has expanded dramatically in the last two decades with average annual 8% growth, and benefited from legal improvements that removed some obstacles to private investment in the industrial sector development. The service sector has also seen an increase especially as regards tourism.

Despite positive international judgements of Vietnam's performance, a series of recent scandals and the impact of the economic crisis have uncovered some serious problems that undermine the country's ability to maintain its position as a model of development, also making its future prospects, which had so far seemed rosy, less easy to predict than expected. The major challenge for the Vietnamese economy is, in fact, a deelply rooted and widespread **corruption** that, according to a recent article by Newsweek, has turned the country from an Asian tiger economy, a smaller version of the Chinese giant, into an example of how the **mismanagement of sudden massive capital inflows** can negatively impact on an opening economy.

In particular, the global economic turmoil has brought to surface the indebtment of large state owned enterprises that have been targeted by government funds and also by foreign investment especially after Vietnam's admission to the World Trade Organization in 2007. Corruption scandals have invested many officials and entrepreneurs and overinvestment in inefficient enterprises and conglomerates, as well as in the property market, has drained resources away from the sectors where interventions to boost productivity were most needed. In a recent release Bloomberg highlights how the soaring prices and reduced credit available as banks were tied to funding state monopolies caused the slowdown of the country's economic growth and put it at risk of falling into the so-called "middle-income" trap, with productivity outpaced by costs.

### **General Figures**



Source: General Statistic Office of Vietnam \*All figures except GDP are for January-September 2012 Industry has expanded dramatically in the last two decades with average annual 8% growth, and benefited from legal improvements that removed some obstacles to private investment in the industrial sector development

The government is making efforts to introduce reforms and a legal framework that can create a more favourable business environment and adopted an Anti-Corruption Law in 2005 that implements several measures to counteract the phenomenon. However, the results haven't been as good as wished due to lack of enforcement and limited accountability of financial institutions to the civil society. Government representatives recently stated that restructuring of state companies is underway, but the road is long and tough, and several powerful groups of interest put obstacles on the way.

Despite the important signals that the Vietnamese economy and society are at a critical turning point, which will determine whether the country will be able to attain the upper middle-income bracket in a near future, the improvements brought to its population by the last three decades of economic development are undeniable. The strength of the export sector has helped many to reach a good income level during the booming years, but on the other hand the spill-over effects haven't spread evenly across the country.

Experts warn that Vietnamese government needs to fully commit itself to reform the financial sector and the economy in a more regulated and sustainable way in order to continue on the development path and keep attracting investors that are increasingly turning to faster-growing neighbours such as Philippines or Indonesia. In 2011 FDI grew by 31% in Malaysia and Indonesia and by an estimated 89% in Myanmar, while in Vietnam it dropped by 7%; moreover, the total amount of FDI fell 28% in the first nine months of 2012. This shift in international investors' attitude is attributed in part to the difference between Vietnam's potential and its real performance, and also to the country's downgrade by Moody's who cut its debt's rating to the same level of Cambodia, five levels below Indonesia.

However, although it lost several places in the global competitiveness index, Vietnam is still an attractive investment destination especially for those companies who wish to relocate from China, considering it too expensive. As reported by the consulting firm Dezan Shira and Associates, the South-eastern region has attracted the largest quantity of foreign direct investment so far, followed by the Red River Delta whose FDI inflow was double than that scored by the North and Central Coasts together. The Mekong River Delta, Central and North-western regions instead attracted little FDI. These trends have recently been shifting towards an increased attention to formerly neglected provinces.

Three key economic zones have been pointed out as leading areas for the country's economic development until 2015, namely the Northern, Central and Southern Key Economic Zone. In such areas the annual average per capita income is expected to increase to US\$3,000 and trade revenues are targeted to rise by 14% a year. Their performance in the period 2006-2010 was markedly positive, with annual GDP growth rate of 10.8%, per capita income averaging over US\$1,600 (well above national average), an 89% share of the country's total import-export value (US\$602 billion), and over 90% of the total foreign investment projects in Vietnam (12,478 projects, US\$162 billion).

Woman working in a rice field in spring in Vietnam sklyarova iryna / Shutterstock.com



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### • • • Northern Key Economic Zone

#### Municipalities: Hanoi City, Hai Phong City

Provinces: Hung Yen, Quang Ninh, Hai Duong, Ha Tay, Bac Ninh, Vinh Phuc.

This area was marked for the development of industrial parks and high-tech zones among which the Vietnam-Singapore Industrial Park in Bac Ninh Province is going to host the new Nokia Vietnam manufacturing facility that is being developed on an area of 17 hectares and expected to become operational in early 2013.

### •••Southern KEZ

### Municipalities: Ho Chi Minh City

Provinces: Binh Duong, Ba Ria – Vung Tau, Dong Nai, Tay Ninh, Binh Phuoc, Long An.

The Southern region as a whole is a major contributor of national GDP and the driver of the country's modernization. The Southern KEZ focuses on the development of trade, telecommunications, tourism, finance, banking, services, technology, culture and training, as well as commodities from industrial crops and animal husbandry. Moreover, Southern KEZ targeted for oil and gas exploration and electricity generation. It is worth mentioning that Vietnam is the third largest oil producer in Southeast Asia. Infrastructural works are essential to these plans, considering that the region is a major hub for the national sea, air and urban transportation system. Major Vietnamese ports and the country's largest airports such as Tan Son Nhat International Airport, the new Long Thanh Airport (to become operational by 2020), Saigon Port and the Vung Tau – Thi Vai Port Complex are all part of the plans for an upgrading of the transpiration system.

### •••Central KEZ

#### Municipality: Da Nang City

**Provinces:** Thua Thien Hue, Quang Nam, Quang Ngai, Binh Dinh. The region is considered as Vietnam's "growth nucleus" to boost development in the Central Highlands.

Industries that are targeted for promotion and investment include maritime economy related activities such as shipbuilding and coastal tourism development, oil and gas and high-tech industries.

Beautiful view on the mountain from the grotto. Tam coc national park. Vietnam Khoroshunova Olga / Shutterstock.com

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### Health Facilities, 2011

Number of health establishments	13484
Number of hospitals	1059
Number of regional polyclinics	567
Medical service units in communes, precincts and ministries/agencies	11787
Number of patient beds	248,000
Of which in hospitals	178,600
Of which in regional polyclinics	7,300
Of which in medical service units in communes, precincts and ministries/agencies	56,200
Patient beds per 10000 inhabitants, excl. in medical service units	21.8

Source: 2011 Statistical Handbook

### **Health Workforce**

Doctors	62,000
Assistant physicians	52,600
Nurses	94,700
Midwives	28,700
Doctors per 10000 inhabitants	7.1
Pharmacists of high degree	5.500
Pharmacists of middle degree	20.200
Assistant pharmacists	6.400

Source: 2011 Statistical Handbook

### Healthcare system

The Vietnamese healthcare system is based on three levels of healthcare delivery: the **Ministry of Health** administers central and regional hospitals; **the provincial health departments** (PHDs) manage both provincial-level and district-level providers; **district health offices** (DHOs) administer commune-level providers. The service delivery network has wide coverage, with commune-level health centres acting as first formal point of health care and delivering primary health care services such as early detection of epidemics, common diseases treatment and prevention and health promotion activities at the village level.

Hospitals and clinics at the central and provincial level often face an overload of patients, while the reverse happens at district and commune **level since people tend to bypass lower levels of care and prefer to access higher levels directly, although the overcrowded facilities.** A reason for this behaviour is that lower levels of care lack specialties and are often poorly serviced and equipped, while at the same time charging only slightly lower user fees compared to hospitals. There is also a geographic discrimination at the provincial level, as healthcare units in the large urban areas of Ho Chi Minh City and Hanoi have better and more modern equipment than health centres in other provinces.

Vietnam has achieved several important improvements in health indicators such as life expectancy, child mortality and incidence of tuberculosis, although life expectancy of people living in disadvantaged regions, like the Northeast, Northwest and Central Highlands is lower than that of people living in areas with better socioeconomic status like the Southeast, North Central Coast and Red River Delta.

Health expenditure has grown significantly in the last decade: per capita health expenditure has increased four-fold and total health expenditure rose annually by 9.8%, a higher rate than the annual GDP growth,

and currently at 6.4% of GDP. However, government funding is comparatively low by ASEAN standards, with per capita spending on health below that of Malaysia, Indonesia and the Philippines.

The tax-based health system has shifted to a system financed by government revenues, social health insurance and out-of-pocket payments. The health insurance market is dominated by a state-owned company and the lack of competition doesn't help the scheme fully meet the health needs of the Vietnamese society; therefore, most health and hospital expenses still have to be met out of pocket. Private health financing accounts for 55-60% of total health expenditure and despite the significant drop from 80.5% in 1998, it still remains one world's highest. Moreover, this figure does not take into account the informal fees, which represent a significant proportion of hospital fees and a major source of revenue for public hospital staff. Other minor sources of health financing are external aid, overseas development assistance and private health insurance.

The government aims to achieve universal health coverage by 2014 and is reshaping its health financing and insurance system to reach the goal. It is a big challenge indeed for the third most populous country in South-East Asia, but an important step in this direction was the introduction of the **Health Insurance Law** that came into effect in 2009. **60% of the population is currently covered by the social health insurance.** 

The government funds health providers budgets and takes care of network upgrading, however, starting from 2006, the implementation of hospital financial autonomy reduced such funding to essential public health and primary care, and certain parts of recurrent expenditures of tertiary care. The money saved from such reduction was used to subsidize the enrolment of vulnerable population groups such as poor and children in the social insurance system.



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According to Vietnamese media by the end of last year only 1.6 million near-poor people (those with monthly income of US\$19-24 in rural areas, and US\$23-30 in urban areas) bought insurance, about 26% of the group. 6 million of people are going benefit from a US\$113 million package to subsidize social insurance, which should increase the share of insured near-poor people to 40%. In June, government's subsidy was increased from 50 to 70% of the annual premium, but the remaining 30% is still difficult to afford for many people in this group and government officials claimed it should be provided by capable localities.

The USAID report "Assessing Provincial Health Systems In Vietnam" analyses the impact of the broad commercialisation of social and health services that followed the market-oriented economic reforms and highlights that although for the wealthier social groups healthcare provision in Vietnam is better and treatment standards have improved, these benefits have not been evenly distributed. The 35 million Vietnamese that are still uninsured risk to fall into poverty when encountering major medical expenses, while the 53 million insured often need to pay informal fees to health staff and experience corruption at local health services. According to a survey, 70% of interviewed medical staff admitted to have asked patients for bribes. Poor groups are all the more disadvantaged by such practice and have therefore limited access to healthcare services.

#### Other critical points include:

•Uneven distribution of doctors and professionals in rural and poor urban areas compared to major urban hospitals where the relatively wealthier population seeks care; most of the best health workers are concentrated in the larger hospitals in Ho Chi Minh City and Hanoi.

• Overprescription of drugs and laboratory tests whose price is raised once they are included in the insurance lists, a practice that also places a burden on the National Health Insurance Fund since medication accounts for 45-60% of all hospital costs.

•Shortage of qualified pharmacists and oversupply of ill-regulated pharmacies

Although public spending on health has increased, about 70% of the funds go to curative services at higher level (central or provincial), while primary care and preventive services in rural areas and at the commune level are underfunded. The above mentioned report claims that major reforms including fee-for-service mechanism, removal of negative incentives available to service providers and a reduction in informal and corrupt procedures in the health service and insurance refund system are essential to face the rising healthcare costs and service demand and to create a more efficient and equitable healthcare system.

### The market for medical devices

In 2012, the Vietnamese market for medical equipment and supplies is estimated at **US\$634** million, about US\$7 per capita. Future growth prospects for the medical device market are tied to the extension of the universal healthcare coverage, that is expected to increase the demand for quality health services, together with the demographic growth rates. According to Austrade, Vietnam's medical device market is estimated to be **growing at an annual 10.3%**, favoured by a comparatively faster and cheaper regulatory system than in China or Japan, but a recent Espicom report on the Vietnamese medical market to US\$1.5 billion in five years.

According to Espicom, over **90% of the market is supplied by imports,** dominated by Japan, Germany, China and the USA that accounted for 42.6% of imports in 2011. Locally produced medical products remain at a basic level, with exports valued US\$420million in 2011, 34.2% of which towards Japan. Many overseas companies, and especially Japanese, use the country as a manufacturing base, which accounts for the export growth.

Government-funded hospitals account for 70% of medical device purchases, but there is also an increasing share of sales to foreignowned hospitals and clinics although they usually source equipment produced by their sponsoring country. Government hospitals can purchase medical devices directly up to an amount of US\$5,700, beyond which they have to go though a bidding organised by the MOH. Foreign companies must appoint a local partner in order to participate to a tender.

**Private hospitals or clinics buy directly from local distributors.** The private healthcare sector in Vietnam has expanded since the private practice was allowed in 1989, as for those who can afford to seek care in private facilities, the quality is superior to state providers. Although the government is encouraging private participation into the healthcare system, it has also allocated US\$2.5 billion for the construction or upgrading of specialty hospitals and some provincial-level general hospitals in disadvantaged areas in the 2009-2013 period.

Foreign participation in the private healthcare sector is dominated by French and US companies, mainly running international hospitals and clinics in the major urban centres especially targeting the wealthier population, such as the Franco-Vietnam Hospital in Ho Chi Minh City. However, despite the increased availability of international standard health providers, each year over 30,000 Vietnamese travel abroad to destinations such as China, Thailand and Singapore to seek medical treatment, accounting for the important opportunities for investment in healthcare services that may meet this group's demand for health services.

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### North **69**

GDP, 2011 US\$30 billion

### 24.6 million

Life expectancy males 65.3 years, females 73.2 years

Real annual GDP growth,

26.2/1,000

Source: 2012, CIA World Factbook

0.8%

### South Korea

& South Korea

he Democratic Republic of Korea (known as North Korea) is one of the most isolated and authoritarian countries in the world, ruled by a centralized government under the control of the Korean Workers' Party headed by a family dynasty of

M Outlook on North

dictators. All media are controlled by the government and heavily censored, correspondence is monitored and only the party elite can access the Internet, while mobile phone access is limited to an internal network, although it registers above one million users. International calls are only available to foreigners and politic officials. North Korea is ranked second-to-last on the World Press Freedom Index.

Unlike its neighbour, North Korea has failed to introduce economic reforms that could help the country's development, rather pursuing a "military first" strategy focusing all resources on heavy industrialization for military purposes. As North Korea has not published economic data since mid-1960s, or has submitted only intermittent and unreliable reports, all obtainable estimates are sourced by outsiders such as the Bank of Korea or UN. According to the most recent estimates, per capita GNI is around US\$300-500. Nominal GNI was valued at 32.4 trillion won for 2011, only 2.6% of the South Korean economy, while GNI per capita stood at 1,334 million won, approximately one nineteenth (5.3%) that of South Korea.

The country ranks last in the economic freedom index, and there aren't any signals of intentions to open or restructure the economy. The state owns all companies and almost all property, Even the timid measures towards an opening to market reforms in the last decade have recently been withdrawn and the forms of private market have been further reduced, worsening people's life conditions. After the mass starvation in the 1990s caused by the wrong economic policies, a currency revaluation in 2009 wiped out savings for much of the population.

North Korea largely depends on China and South Korea for economic aids and food and medicines donations have long been the only means of survival for millions of North Koreans, except from government and military elites. Military and government officials divert food aid from international donors and demand bribes before distributing it. For the small part of foreign trade, South Korea is the second trade partner after China and the main export market. However, South Korean aid and trade towards the North as diminished after new tensions arose on the North Korean nuclear program. The only foreign participation allowed is reduced to investment in special economic zones after case-by-case approval.

The economic zones next to China are subject to particular attention, as North Korean officials claim to look with admiration at the Chinese model of development, although opening and reforms are not yet even spoken of in Pyongyang. Nevertheless, such experience makes Chinese enterprises particularly welcome, and they are actually signing multimillion-dollar business deals to extract resources and build and repair infrastructure. One of these special zones, known as "Rason", 30 miles from the Chinese border, combines the two coastal towns of Rajin and Sonbong that should attract foreign shipping, seafood processing and assembly plants.

According to the New York Times, some analysts argue that "North Korea could be establishing here the kind of laboratory that the Chinese Communist Party set up in the fishing village of Shenzhen in 1980 to help move China forward. The State Development Bank and the Taepung International Investment Group have been established with the aim of bringing in foreign investment. However, even with potentially advantageous conditions such as limited concurrence and government cooperation, investors that have long been observing North Korea are diffident and feel that conditions are not yet mature. Currently, transportation infrastructure, lack of Internet connection, power shortages and authoritarian practices such as confiscation of foreigners' mobile phones are all obstacles to investments.

Population 50 million

ith Korea

Real annual GDP growth, 2011 **3.6%**  Life expectancy

GDP, 2011

trillion

US\$1.116

Infant mortality rate

4 per 1000

in 2011

Source: 2012, CIA World Fuctboo

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BMI Biomedical International s.r.l. Via E. Fermi 52 Q/R 24035 Curno (BG) - Italy As regards healthcare, there is a marked difference between what official claims state and the reality. Nominally, medical treatment is provided free of charge to all citizens, and some general figures are also good, with one doctor every 304 inhabitants and one hospital bed for every 78; however, a report prepared by Amnesty International and based on extensive interviews with North Korean refugees opens a window on the real health status of the majority of the population, which is under continuous threat.

The combination of natural disasters, limited cultivable land and economic mismanagement, a bad famine hit the country in the early 1990s and brought about a million people to die of starvation. The government then started to encourage the population to eat wild foods such as roots, grasses, stalks and tree bark, claiming that they were healthy and safe. As the food shortages worsened, wild foods including varieties, that can be poisonous or cause severe digestive problems, became a consistent part of many North Koreans' diet, and by 1996 the UN estimated that they accounted for some 30% of it. Still nowadays, in the lean months, households often mix wild foods with grains, such as corn or rice, in order to make their limited food supply last longer. According to Reuters, Pyongyang keeps spending most of its earnings and often also diverts aids towards its million-strong army and the development of nuclear weapons and missiles instead of feeding its millions of malnourished people.

Food shortages are still a common problem and significantly affect general health conditions. Public health information is also lacking and many people do not visit doctors when they are ill, or if they do, they cannot afford more complex treatment. Health facilities are reported to operate with frequent power cuts and no heat. Even basic medicines and essential sterile disposables are missing, and because medical personnel often do not receive salaries, doctors charge illegally for their service, thus excluding the poor from medical care and medicines. Witnesses even said that surgery is often performed without anaesthesia. In consequence of the newly arisen tensions between the two Koreas and with the USA, the two biggest donors, it is now even more difficult for aid organizations to supply food and basic medicines to the North Korean people. Unless a change in the party's aggressive and mismanaging policy occurs, there are minimum hopes for a fast resolution of the crisis.

### South Korea

The demilitarised zone (DMZ) between South and North Korea is the world's most heavily-fortified frontier. Right beyond it, a totally different world from the totalitarian North makes the difference between the two countries even more striking.

Only about 190 km away from Pyongyang, Seoul is one of the most modern metropolis in the world, the capital of one of the major world economies and among the most affluent Asian countries. Its 50 million population enjoy average life expectancy of 81 years, a per capita gross national income of over US\$22,000 and a GDP that topped US\$1.116 trillion in 2011 and grew by despite the global crisis.

As far as healthcare is concerned, the contrast is also sharp. The South Korean healthcare system is based on a compulsory national health insurance established in 2000 from the integration of several existing health insurance funds. funded by taxes, integrated by private health insurance that cover additional expenses.



All citizens must enroll in the national health insurance except particular categories who receive care without paying any premiums (such as very poor people, refugees, children and other specifically defined groups). Employed people have half of the premium deducted from their earning and the other half contributed by the employer, while the others must pay directly to the National Health Insurance Corporation (NHIC), the government-run administering body. The premiums vary according to income.

The NHIC establishes the cost for covered medical procedures that basically include all treatment except elective procedures and optional expenses. Medicines are also covered including traditional remedies and semi-medical treatment, as alternative medicine is an important part of the country's health system. Besides the National Health Insurance, the Medical Aid Program covers around 3.7% of the total population.

According to figures released by the OECD, South Korea health expenditure was 7.1% of GDP in 2010, up from 4.5% in 2000, while average spending per capita was US\$2,035 (at purchasing power parity), but still low compared to other developed countries. In the last decade health spending grew on average by annual 8%, driven by an increase in public expenditure on health that reached 58% in 2010. The private share of health funding is largely made up by out-of-pocket payment, accounting for about 32%.

Healthcare services are mainly delivered by private providers, as around 90% of total medical institutions are private facilities. In 2007 were recorded 52,914 health facilities, 1,536 of which were hospitals (including general, oriental and dental hospitals), and over 450 thousands hospital beds. As of 2007 there were about 91,400 physicians, 23,100 dentists, 16,600 oriental medical doctors, 57,000 pharmacists and 235,000 nurses in South Korea. Although the number of health workers has increased, per capita density remains low. OECD also reports that diagnostic technologies such as CT scanners and MRI experienced a rapid growth in South Korea:

• The number of CT scanner per million population increased from 12.2 in 1990 to 35.3 in 2010

• The number of MRIs per million population increased from 1.4 in 1990 to 19.9 in 2010.

### Health care services are provided at two levels: primary care is delivered at clinics and hospitals, secondary care is available in 43 tertiary hospitals through a referral from a primary care physician.

92 hospitals, 251 health centres, 1,314 sub-public health centres and 1,908 primary health care posts carry out public health functions.

Dental care is covered under the NHI system, but since a number of treatments are excluded from the benefit package, they need to be paid for directly out-of-pocket. The government has announced that it will expand the insurance coverage budget by 1.6% to cover, among the others, additional dental treatments such as partial dentures, cleft lip surgery and removal of dental calculus.

The predominantly private health facilities are mostly located in urban areas, as well as 92% of physicians and 90.8% of hospital beds do. Although the urbanization rate is also high at about 80%, there is still a disparity between well covered cities and rural areas.



### Summary of South Korean healthcare resources, 2007

Medical Doctors	91,475		
People Per Doctor	530		
Dentists	23,126		
Nurses	235,687		
Pharmacists	57,176		
General Hospitals	302		
Hospitals & Clinics	27,803		
Dental Hospitals & Clinics	13,431		
Korean Traditional Hospitals & Clinics	11,033		

Source: OSEC, OECD

Another challenge to the South Korean health system is the expected increase in medical expenditure tied to the rapidly ageing society, as elderly already account for about a third of costs borne by the NHIC. The financial burden posed on the younger population is being targeted by reforms such as the introduction of the Long-term Care Insurance Program. The market for medical devices was estimated at US\$3.4 billion in 2009, a relevant share of which is given by the strong domestic production especially in the mid-price market, whose improving quality is often replacing imports. Local manufacturers are also generally favoured by government policies, but the signature of Free Trade Agreements with the European Union and the USA is expected to facilitate trade by the reduction of tariff and non-tariff barriers.

The market grew on average by 9.7% in the period 2004-2009. According to Espicom, imports reached US\$2.8 billion in 2011, growing 12.6% over the previous year, with double digit growth for almost all device categories except diagnostic imaging (3.7%), the second largest category at US\$803 million, and orthopaedics (9.8%), valued at US\$195.2 million. On the contrary consumables rose by 22.2% to US\$437.2 million.

### Author: Michela Adinolfi

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### Top 20 medical devices manufactured in South Korea, 2009

No	ltem	No. of manufacturers	% on total production	
T	Ultrasonic imaging system	5	10.37	
2	Dental precious metal alloy	39	9.19	
3	Dental implant	28	6.48	
4	Sight corrective ophthalmic lens	34	6.06	
5	Heator medical use by personal	23	4.75	
6	Medical image processing unit	36	2.81	
7	Soft contact lenses	30	2.61	
8	Probe for medical use	11	2.55	
9	Digital X-ray imaging system	11	2.49	
10	Combinational stimulator for medical use by personal	82	2.49	
11	Syringes for general use	16	2.33	
12	Laser surgical apparatus	43	2.10	
13	Computed tomography X-ray system	5	1.94	
14	Dental unit and chair	10	1.69	
15	Spinal interlaminal fixation orthosis	17	1.42	
16	Blood glucose strip	8	1.29	
17	Intravascular administration set	12	1.23	
18	Hospital bed	24	1.21	
19	Splint	60	1.15	
20	Hearing aid	28	1.03	

Source: KMDIA



··· International Market & Trends

### Top 20 medical devices imported in South Korea, 2009

No	ltem	No. of importers	% on total imports
1	Stent	26	4.95
2	Knee joint prosthesis	13	3.56
3	Soft contact lenses	12	3.20
4	Computed tomography X-ray system	14	2.93
5	Dialyzer for haemodialysis	12	2.51
6	MRI system	6	2.37
7	Accelerator system collimator electron applicator	5	2.24
8	Sight corrective ophthalmic lens	33	2.21
9	Staple for medical use	14	1.90
10	Surgical instrument	55	1.70
11	Ultrasonic imaging system	23	1.66
12	Hip prosthesis	16	1.59
13	Dental implant	35	1.58
14	PET system	4	1.54
15	Spinal internal fixation system	21	1.48
16	Intraocular lenses	14	1.46
17	Probe for medical use	74	1.35
18	Trocar	39	1.27
19	Wound dressing prosthesis	44	1.22
20	Angiographic X-ray system	3	1.11

Source: KMDIA



# Healthcare in French Polynesia

€21.4 billion (2011)Of which invested in R&D: 9% 5% >65% Number of 11.000 175,000 Of which employed in R&D: 15% Source: UN-OHRLLS

ocated about 6,000 km off the Eastern Australian coast, French Polynesia is an overseas country of France annexed during the 19th century, that comprises five archipelagos of 35 volcanic islands and about 183 coral atolls. The closest neighbour is Kiribati to the northwest and Cook Islands to the west.

Since February 2004 French Polynesia has become an overseas country within the French Republic with constitutionally guaranteed autonomy, democratically governed by its representatives and by local referendum.

Distribution of population across the Frei	nch Polynesian archipelagos
lles du Vent (Winward Islands)	75%
lles sous le Vent (Leeward Islands)	12%
Marquises (Marquesas Islands)	4%
Australes (Austral Islands)	3%
Tuamotu Gambier	7%

Around 88% of the population lives in the Society Islands, the administrative region comprising Winward and Leeward Islands. The capital, Papeete, is located in the biggest and most populated island, Tahiti, in the Winward Islands archipelago, and hosts all governmental institutions as well as being the business hub of the country. 82% of the whole country's population lives in Tahiti. Although the road transportation system is in place, the lack of an adequate public transport system requires the use of rental cars and taxis. The other islands can be reached by flight with the local Air Tahiti or through ferry service for closer islands such as Moorea.





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The World Bank categorizes French Polynesia as a high income country. In the last half century the economy has shifted from agricultural subsistence to military industry, propelled by French military presence for nuclear testing, and tourism driven activities. Transfer payments from France account for about 35% of GDP.

However, since the stop of nuclear tests in 1996 tourism has remained the only major source of revenues, accounting for about a quarter of GDP. Other economic activities include pearl farming and deep-sea commercial fishing, while there is a small local food processing industry, but trade is unbalanced with imports far exceeding the very limited exports.

The WHO calculates that 10% of GDP is spent on healthcare. The majority of population has access to quality health care in medical and dental facilities, pharmacies, private clinics and a large government hospital in Tahiti. The outer islands have hospitals or dispensaries, and a few private practitioners. This results in good immunisation coverage, with over 95% levels, and low infant and maternal mortality rates (5 per 1,000 live births and I per 4,434 births respectively). French Polynesians are on average a young population, with 34% below 20 years of age and only 6% above 65 years.

However, the islands need a constant monitoring on epidemics of tropical and communicable diseases that often outbreak in the region such as dengue fever, influenza, leptospirosis and lymphatic filariasis as well as tuberculosis to a lesser extent.

Noncommunicable and chronic diseases have also been increasing in recent decades due to changing lifestyles; obesity prevalence is high among adults (42%) and children (10%) and cardiovascular disease

and cancer are responsible for half of all deaths, as well as being the main causes of premature mortality (before 65 years). Under this trend, the need for specific and specialized long-term care and treatment programmes led to the construction of a new hospital for modern oncology and cardiology services, despite the consequent increase in hospital expenses.

The total health spending in 2008 amounted to over US\$884 million, 55% of which came from government contribution (over US\$518 million). Health spending is estimated to grow by 7% a year, also in consequence of increased access to new technologies. There is a US\$13-15 million budget for prevention activities funded by sugar and alcohol taxation, but resources dedicated to prevention activities are insufficient compared to curative interventions, and public health awareness is low especially regarding alcohol and drug consumption.

French Polynesians are covered for medical expenses under a social program known as Protection Sociale Généralisée, under three different kinds of programs (employed, not employed and solidarity regime). There are also 18 diseases that have been recognized by law to be a consequence of nuclear tests carried on in the territory, which are entitled to treatment as well as reimbursement.

The provision of health services is complicated by the high fragmentation of the territory and the dispersion of population over 121 islands. While people living in Tahiti have no difficulty in reaching the main hospital in Papeete, inhabitants of the more remote islands receive treatment at the Dispensaire, a French government run clinic, but they need to be transported to Tahiti in case of severe illness, and even outside Polynesia for complex surgery or other unavailable treatment.

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Moreover, medical personnel density varies greatly among the different archipelagos. For instance, Tahiti has 210 physicians per 100,000 inhabitants, while the Austral Islands only have 44. Tuamotu-Gambier and Marquesas Islands have similarly low ratios. To face such disparities, one to two nurses have been assigned in about 20 isolated communities where there is no doctor and given responsibility for local coordination of public health programmes.

The hospital system includes five public and four private hospitals, including one for ambulatory treatment and one for physiotherapy. 115 public health facilities (dispensaries, medical centres, aid posts) are spread across all archipelagos and are managed by the Health Directorate, employing 1,200 workers are employed including 116 doctors and 340 nurses. The public hospitals include:

• The Main Hospital of French Polynesia (Centre Hospitalier de Polynésie Française), run directly by the Ministry of Health, which is the referral hospital offering emergency services, neurosurgery, oncology and cardiovascular surgery, including intensive care services; it employs about 1,060 workers including 143 doctors and 508 nurses;

• Four "proximity hospitals", managed by the Health Directorate: one in Tahiti, in the city of Taravao, three other in the islands of Moorea, Raiatea (Leeward Islands) and Nuku Hiva (Marquesas Islands).

The private system employs 230 doctors and 255 nurses. Facilities are mainly concentrated on the Windward Islands and the Leeward Islands, in four main facilities: Cardella and Paofai clinics, Te Tiare health centre and the Mamao ambulatory. Although the private sector also provides primary care, only a limited number of private health professionals (medical practitioners, nurses, physiotherapists, dentists) have an agree-

ment with the Social Health Insurance scheme to provide refunded services. On the majority of islands, especially the more remote ones, healthcare is available exclusively through public providers.

According to local media, Polynesia's medical system is in crisis due to excessive costs of the health insurance scheme that exceeds the salaries of the scheme's doctors to provide care, which brought to quarrels between doctors and both the health ministry and insurance administrators. Moreover, government budget shortage caused delays in payments to suppliers.

Author: Michela Adinolfi

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# Initial registration of import products in China

### Direction for the Application Form of Registration

I. All the contents must be filled in in both Chinese and English;2. Upon the application, the form must be printed;

3. All the items must be completely filled in, and as for the vacant items, "/" must be used to show inapplicability;

4. The Name of Devices and Model, Name and Address of Manufacturer must be the same as in the documents approved by the government of the Country of Origin, and consistent with the contents concerned in the test reports, operation manual of the product, and so on;

5. The enterprise must not set up the format for the Application Form for Registration without authorization. The Application Form is available here: http://www.sda.gov.cn/ylqjzc/setup.exe

### **Application Documents**

### I. Certificate of the legal production qualification of the Manufacturer.

a) The certificate issued by the government agency of the Country of Origin to authorize the Manufacturer to engage in the production and distribution of medical devices (equivalent to the business certificate or manufacturing enterprise license). b) The copy of certificates may be submitted, sealed by the original issuing agency or notarized by the local notarization agency.

### 2. Qualification certificate of the applicant

a) Business certificate;

b)The certificate of commission given by the manufacturer to the agent for registration

# 3. Certificate recognized or approved by the government of the Country of Origin to authorize the products as medical devices to enter into the market of the country.

a) The certificate recognized or approved by the government of the Country of Origin to authorize the products as medical devices to enter into the market of the country.

In case of any special authorization documents specified by the government of Country of Origin for medical devices to be put into the market of the Country of Origin such as US FDA 510 K or PMA and EU CE certificate, they must be submitted.



### In case of one of the following circumstances:

• That no special authorization documents are required to handle by the government of the Country of Origin;

• That in case of any change to the Products on the basis of the Products specified in the original special authorization documents, due to the difference in the partition of registration elements, no re-application is required by the government of the Country of Origin

### The enterprise shall give a statement, and provide the following certificates:

i. The free sale certificate issued by the government or the certificate to the foreign government;

ii. The enterprise self-guarantee declaration in conformance with the provisions concerned of local regulations

### b) In case of no document issued by the government of Country of Origin to authorize the medical devices to be put into market

• If the products are regulated as medical devices in the Country of Origin, but they have not been authorized to be put into market, the Standards of the Products to be Registered authorized by the competent department must be submitted; in case of Products of Class II or Class III, the full-performance test report, Clinical Trial Reports, risk analysis reports within the territory of China and other documents necessary for the registration of import products must be submitted. If the application is accepted, the on-site inspection of the production quality system will be arranged.

• If the products are regulated as medical devices in the Country of Origin, but don't need authorization to be put in the market because they are produced specifically for China, please refer to par. a)

• If the products aren't regulated as medical devices in the Country of Origin but the Products are defined as medical devices in China, please refer to par. a)

c)The copy of certificates may be submitted, sealed by the original issuing agency or notarized by the local notarization agency.

### 4. Standards of the Products to be Registered applying the Provisions for the Management of the Medical Devices Standards

a) Implementation of "Only the Original of the Standards Sealed or Signed by the Legal Representative may be submitted":

• Standards of the Products to be Registered may be sealed through the following three methods:

i. to be sealed by the manufacturer;

ii. to be sealed by the office or representative office of the manufacturer in China.

iii. to be sealed by the unit in charge of the conclusion, arrangement, drafting of the Standards of the Products to be Registered commissioned by the Manufacturer. And in the certificate of commission, it must be clearly indicated that "the Unit is commissioned to be responsible for the completion of the Standards of the Products to be Registered in China, and the Manufacturer shall be responsible for the quality of the Products".

• The definition of the Legal Representative: in accordance with the international practices, "the signature and seal of the Legal Representative" of the manufacturer abroad may be signed and sealed by the senior official in charge of the corresponding business activities.

b) Standards of the Products to be Registered are reviewed, codified, and recorded by SDA Standard and Technical Committee;

c) As for the products with national standard and industrial standards, the manufacturer is required, according its own specialties, supplement and corresponding requirements, to formulate the Standards of the Products to be Registered, and assure the safety and effectiveness of the operation of the Products;



If the enterprise thinks that no requirements on safety need to be added, and that the direct adoption of national standard and industrial standards is sufficient, the manufacturer must submit a statement justifying that without any increase and improvement in the standard index on the basis of national standard and industrial standards, the safety and effectiveness of the products for application can be assured, declaring to bear the quality liabilities after the launching of the products and carrying the model, specification of the Products.

As for the products with ISO or IEC standards, the manufacturer has to convert the standards to the Standards for the Products to be Registered.

### 5. Operation Manual of the Products

a)Implementation of "Only the Original of the Operation Manual Sealed or Signed by the Legal Representative may be submitted":

• The Operation Manual of Class II or Class III products must be sealed by the Manufacturer; Class I products manual must not.

• Definition of the Legal Representative: in accordance with the international practices, "the signature and seal of the Legal Representative" of the manufacturer abroad may be signed and sealed by the person in charge of the corresponding business activities.

b)Implementation of the "Administrative Provisions on the Operation Manual of Medical Devices". The operation manual of medical devices must implement the national standards provided in "Operation Manual for Industrial Products - General provisions". In accordance with the specialty of the medical devices, they include:

I. Name of Product, Name, Address, Postal Code and Tel. of the Manufacturer;

2. Registration number of the products;

3. Applied product standards;

4. The main structure, performance, specification of the Products; the usage, scope of application, contraindication , precautions, cautions and suggestions of the Products;

5. Interpretation of the figures, logos, abbreviations, etc. of the labels and marks;

6. Illustration and graphic expression of the Installation and Operation; 7. The Maintenance methods, special storage methods and length of life of the Products;

8. Other necessary contents specified in the Product Standards.

6. Type test Report presented by the medical devices quality test agency recognized by the State Drug Administration within the recent one year (Applied to the Products of Class II and Class III)

- a)The following import products may apply to Test-after-Registration:
- I. X-Ray Computerized Topography (CT);
  - Positron Emission Computerized Topography (PET);
- 3. Single Photon Emission Computerized Topography (SPECT);
- 4. Extraneous Shock Wave Crusher;
- 5. Color Ultrasonic Diagnostic Scanner;
- 6. Large Laser Therapy Apparatus;
- 7. Large X-Ray Diagnostic Equipment;
- 8. Automatic Biochemical Analyzer;
- 9. Cobalt 60 Therapy Unit;
- 10. Gamma Knife;

2.

- II. Medico- electronic Linear Accelerator;
- 12. Simulated Positioner;
- 13. Magnetic Resonance Imaging System

To apply Test-after-Registration of import products the manufacturer must submit an application for the Test and commit to complete the Test at first, as the product gets into the Chinese market. If the product fails to pass the following test, the registration certificate shall be cancelled by the original issuing agency.

b) The test on placing the Products under the competent unit must be determined in accordance with the "government certified Scope of Acceptance for Examination of the Examination Center". The enterprise may at its option select one among the qualified examination centers. In case of any ambiguity on the catalog, the manufacturers submits a written report to the office of acceptance that will deliver the case to the competent department to designate one center for test.

c) Under the following circumstances, no test is required:

• For laboratory equipment, the electrophoresis apparatus, centrifuge, Ultra Low temperature refrigerator, paraffin slicing machine, paraffin embedding machine, cell centrifuge smearing machine, and full automatic dying machine.

• For Products of Class I in accordance with catalog of classification of the medical devices Products of China.

d) The application for exemption from test may be made for medical devices meeting the following requirements:

I. The domestic enterprise has received the authentication certificate of GB/T19001+YY/T0287 or GB/T19002+YY/T0288 issued by the quality system authentication agency recognized by the State Drug Administration, and the quality system concerned has covered the Products for application.



The Products abroad has received the authorization of launching from the competent department of the Country of Origin, and the certificate is still valid, and the enterprise has been authenticated in accordance with the ISO 9000 Serial Standards (or equivalent).

2. The difference between the structure and performance of the Products for application and those of the registered products of a kind is insignificant in terms of safety and effectiveness.

3. The Products for application are not implantable device.

4. No radioactive sources exist in the Products for application.

5. In case of any malfunction, no grave injury accidents such as death of and body injury of the user or operator will be caused.

7. The clinical trial report of medical devices, the methods on the provisions of the report should be applied in accordance with the "Provisions for the 'Subitem of Clinical Reports' for the Registration of Medical Devices". The clinical trial shall be implemented in accordance with the "Provisions for the Clinical Trial Management of Medical Devices".

a) Prior to the promulgation of the new Clinical Trial Management Methods, the quantity and trial period of the Clinical Trial must be implemented in accordance with the "Interim Provisions for the Clinical Verifications of Medical Devices" issued by the State Drug Administration in 1997. If in accordance with the requirements the provisions for Clinical Reports are not necessary, the enterprise may make a statement upon the application.

b) Clinical Reports of Import Products in the Country of Origin may be provided through the following two methods:

• Clinical reports required upon the authorization of launching by the Country of Origin;

• In case that no clinical reports are required upon the authorization of launching by the Country of Origin, the Manufacturer must state that no such reports are required and guarantee the statement authenticity. In the event, the enterprise may submit the Clinical Trial Reports and documents after the launching of the Products.

c) Under the following circumstances, no clinical reports are required: I. For IVD reagents, except IVD reagent approved and registered by Department of Medical Devices for the diagnosis of hepatitis and AIDS, in such case the Clinical Trials will be carried out in designated medical institutions (quantity and statistical methods undetermined); 2. For condom Products; 3. For the laboratory equipment, the electrophoresis apparatus, centrifuge, Ultra Low temperature refrigerator, paraffin slicing machine, paraffin embedding machine, cell centrifuge smearing machine, and full automatic dying machine;

4. For Products of Class I in accordance with the catalog of classification of the medical devices Products of China.

8. Product Quality Guaranty presented by the Manufacturer, to promise that the quality of the products registered and sold in China are unanimously the same as that of the identical products put into market in the Country (Region) of Origin.

### 9. Certificate of commission for the After-Sale Service Agency designated in China, letter of commitment and business certificate of the commissioned agency.

- a) Certificate of commission of After-Sale Services
- Is presented by the Manufacturer;
- The name of the products must be indicated clearly;

• In case of multilevel commissioning, the consignor at every level must provide the certified documents of the Manufacturer.

- b) Letter of commitment
- The contents must be consistent with certificate of commission;
- The letter of commitment must also contain:
- i. Liabilities for reporting the Product quality accidents;

ii. Liabilities for actively contacting with the State competent department in charge of the registration of medical devices;

iii. The qualification certificate of after-sale service units;

iv. Business certificate (the scope of business containing corresponding technical service items) or the registration certificate of the representative agency in China of the manufacturer.

### 10. The Self-Guarantee Declaration on the authenticity of the materials submitted.

- a) Is presented by the manufacturer or its office in China;
- b) Contains a list of the materials submitted;
- c) Contains a commitment on the Liabilities.

Source: State Food and Drug Administration, P. R. China - http://eng.sfda.gov.cn





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# Asia and Pacific Regional Economic Outlook–October 2012 Update

rowth in the Asia-Pacific region has slowed. External headwinds played a major role, as the recovery in advanced economies suffered setbacks. Weaker momentum in China and India also weighed on regional economies. For Asia as a whole, GDP growth fell to its lowest rate since the 2008 global

financial crisis during the first half of 2012. With inflationary pressures easing, macroeconomic policy stances remained generally supportive of domestic demand and in some cases were eased further in response to the slowdown. More broadly, financial conditions remain accommodative and capital inflows have resumed. Going forward, growth is projected to pick up very gradually and Asia should remain the global growth leader, expanding over 2 percentage points faster than the world average next year. However, considerable downside risks remain, in particular with regard to the euro area crisis. The priorities for policymakers are to support noninflationary growth, maintain financial stability, and remain responsive to weaker-than-expected outcomes. Refocusing structural and fiscal reform efforts toward sustained and more inclusive growth remains a priority.

### Growth in Asia has been somewhat lower than previously projected on setbacks to the global recovery

Although a rebound from earlier natural disaster disruptions helped spur growth in the first guarter of 2012, that activity has now slowed markedly (Figure 1). Adverse trade spillovers from weakness in the euro area and beyond have taken their toll on Asian exports. For Asia as a whole, real GDP growth averaged  $5\frac{1}{2}$  percent (year over year) in the first half of 2012, well above the global average, but the lowest rate since the 2008 global financial crisis. Domestic factors also contributed to the slowdown in China and especially in India, reflecting deliberate efforts to engineer a soft landing in the former and weakening investor sentiment adding to supply constraints in the latter. In Japan, a slowdown in consumption drove the recent deceleration in growth after the policy-driven pickup in early 2012. Several Association of Southeast Asian Nations (ASEAN) economies, led by Indonesia, Malaysia, the Philippines, and Thailand, have bucked regional trends, with growth remaining close to potential in part supported by public investment. Australia has also weathered global headwinds relatively well, inparticular as mining-related investment expanded strongly.

# Figure 1. Asia: Changes in Real GDP at Market Prices Quarter over quarter (SAAR) Year over year Year over y

Sources: CEIC Data Company Ltd.; Haver Analytics; and IMF staff calculations

(excl. China)

### Figure 2. Asia: Headline Consumer Prices'

(Year-over-year percent change)



I Latest available data are as of August 2012 except for Korea, Indonesia, Thailand, and Vietnam (September 2012) and Australia and New Zealand (June 2012, quarterly data). Wholesale price index used for India.

### Figure 3. Asia: Credit to Private Sector'

(Year-over-year percent change)



Sources: CEIC Data Company Ltd.; Haver Analytics; and IMF staff calculations. I Latest available data are as of August 2012 except for China, Japan, India, Indonesia, Philippines, and Vietnam (July 2012).

Against the backdrop of weaker activity and declining global commodity prices, headline inflation fell further during the first half of 2012, in many cases within comfort zones (Figure 2). As a result, central banks in the region have either left unchanged or begun cutting policy rates. Largely accommodative monetary policy stances, with real policy and lending rates still 150 basis points below the pre-2008 levels on average, have thus helped maintain favorable conditions for domestic demand. In addition to robust retail sales growth, continuing even at double-digit rates in China, private sector credit growth has remained steady (Figure 3), in particular in many ASEAN economies where credit-to-GDP ratios are above trend. Unemployment, while edging up, has remained close to its pre-2008 lows.

Capital inflows have resumed since the beginning of the summer, reflecting an easing of global financial tensions after a period of heightened volatility in the first half of 2012 (Figure 4). While shifts in portfolio flows were driven by swings in volatile equity flows, Asia's local bond markets have consistently attracted foreign investors, suggesting a relative strength in fundamentals and a dearth of alternative safe stores of value. Indeed, sovereign bonds and CDS spreads have mostly returned to their post-crisis lows. Moreover, the impact of European bank deleveraging in Asia, which appears to have paused in the first quarter of 2012, has had a manageable impact on regional financial systems so far. Claims of European banks are generally moderate relative to other emerging market regions, and funded in many cases by a large domestic deposit base. Growing cross-border activity afforded by healthy balance sheets from banks in the region (including Japan and Australia) has provided an additional buffer.

Asia





Sources: Haver Analytics; and IMF staff calculations.

### The near-term outlook remains subdued, while downside risks may be elevated for longer

Asia's growth is unlikely to pick up in the second half of 2012 as was expected in the April 2012 Asia and Pacific Regional Economic Outlook, given the recent deterioration of a broad range of indicators encompassing activity variables from industrial Asia, the large emerging Asia growth leaders, and the smaller export-dependent economies (Figure 5). Overall, after having slowed in 2011, Asia's growth is forecast to moderate further in 2012 to 51/2 percent, about 1/2 percentage point below 2011 and our April 2012 forecast.

That said, Asia will remain the global growth leader, expanding over 2 percentage points faster than the world average. A modest growth pickup to about 6 percent in 2013 could result mostly from strengthening external demand—itself helped by the recent actions taken by leading central banks— with accommodative macroeconomic policy stances across the region also playing a role (Table 1). Japan would be a major exception, as the lift from exports would be outweighed by the waning impulse from reconstruction spending. Lower-income economies would enjoy significantly stronger growth than Pacific island countries, which continue to face the challenge of building resilience to global and regional developments.

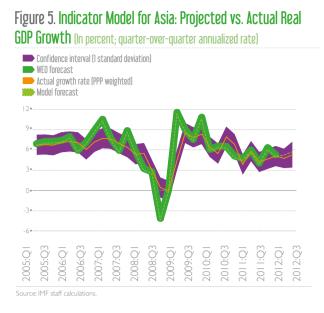
### Table 1. Asia: Real GDP (Year-over-year percent change)

Asia: Real GDP (Year-on-year percent change)

	Actual data and latest projections				Difference from April 2012 WEO	
	2010	2011	2012	2013	2012	2013
Industrial Asia	4.1	-0.2	2.4	1.6	0.2	-0.5
Australia	2.5	2.1	3.3	3.0	0.3 -	-0.5
Japan	4.5	-0.8	2.2	1.2	0.2	-0.5
New Zealand	1.8	1.3	2.2	3.1	-0.1	-0.2
East Asia	9.9	8.2	6.8	7.4	-0.6	-0.6
China	10.4	9.2	7.8	8.2	-0.4	-0.6
Hong Kong SAR	7.1	5.0	1.8	3.5	-0.7	-0.8
Korea	6.3	3.6	2.7	3.6	-0.9	-0.3
Taiwan Province						
of China	10.7	4.0	1.3	3.9	-2.3	-0.8
South Asia	9.8	6.9	5.0	6.0	-1.8	-1.2
Bangladesh	6.4	6.5	6.1	6.1	0.2	-0.3
India	10.1	6.8	4.9	6.0	-2.0	-1.3
Sri Lanka	7.8	8.3	6.7	6.7	-0.7	-0.3
ASEAN	7.6	4.6	5.1	5.5	0.0	-0.5
Brunei Darussalam	2.6	2.2	2.7	1.5	-0.5	-0.1
Cambodia	6.1	7.1	6.5	6.7	0.2	0.3
Indonesia	6.2	6.5	6.0	6.3	-0.1	-0.3
Lao P.D.R.	8.1	8.0	8.3	8.0	-0.1	1.0
Malaysia	7.2	5.1	4.4	4.7	0.0	0.0
Myanmar	5.3	5.5	6.2	6.3	0.2	0.4
Philippines	7.6	3.9	4.8	4.8	0.7	0.1
Singapore	14.8	4.9	2.1	2.9	-0.6	-1.0
Thailand	7.8	0.1	5.6	6.0	0.1	-1.5
Vietnam	6.8	5.9	5.1	5.9	-0.5	-0.4
Emerging Asia <sup>1</sup>	9.6	7.4	6.1	6.8	-0.8	-0.7
Pacific Island						
Countries	1.7	3.6	2.5	2.6	-0.2	0.1
Asia	8.4	5.9	5.4	5.9	-0.6	-0.7



Source: IMF staff projections. I Emerging Asia includes East Asia, India, Indonesia, Malaysia, the Philippines, Singapore, Thailand, and Vietnam.



Partly reflecting the positive growth differential between the region and the rest of the world and the recent appreciation of a number of real effective exchange rates, the overall current account surpluses of both emerging and industrial Asia-while still rather elevated-would remain lower in 2013 than in 2011. Risks to this outlook remain considerable. They are also tilted to the downside, although accommodative global monetary conditions also raise the possibility that growth in Asia might surprise on the upside if European and U.S. policymakers fully deliver on their commitments, Stronger external demand nextyear is premised on a gradual easing of financial pressures emanating from Europe and the avoidance of a "fiscal cliff" in the United States. However, the IMF staff's fan chart for Asia—which uses financial and commodity market data and analyst forecasts to gauge risks—suggests there is now a one in seven chance of Asia's growth falling below 4 percent in 2013, close to the rate last observed in 2009,the year after the Lehman shock (Figure 6).

About two-thirds of emerging Asia's exports (on a value-added basis) are linked to demand from Europe and the United States alone (see April 2012 Asia and Pacific Regional Economic Outlook). Therefore, trade-channel effects, including through the second-round impact of lower investment and employment in export-oriented sectors, would exert a powerful downward drag on Asia's most open economies in the event of a severe global slowdown resulting from a further escalation of the euro area crisis or a fiscal shock in the United States.

While relatively strong economic and policy fundamentals have helped buffer Asian economies against adverse financial market spillovers, aggressive deleveraging by euro area banks and flight of capital to traditional safe havens could also severely disrupt Asian financial systems. ASEAN and East Asian (excluding China) economies would likely be most affected as their financial markets have showed higher financial sensitivities to shocks in systemic advanced economies in the past.

A sudden rise in food or oil prices could also pose downside risks by weakening domestic demand and limiting the scope for monetary policies to support growth. There are already some signs that inflation may be bottoming out following the recent spike of global food prices, although the latter remains much smaller and less broad-based than in 2007/2008. So far, inflation expectations have remained well anchored in most of Asia, helped by relatively stable local rice prices. However, in the event of a further broad-based increase in food prices, the potential for adverse secondround impacts is significant in a number of countries, either due to robust domestic demand, such as in ASEAN economies, or a high share of food and fuel in CPI baskets, including in India and Asia's low-income economies. In these cases there could also be significant budgetary risks from energy and food subsidies, as well as social implications, such as in Pacific Island economies where past gains in poverty reduction would be threatened. For many economies in the Asia-Pacific region, IMF staff estimates put the pass-through from higher global food prices to CPI inflation at 10-20 percent a year after the shock.

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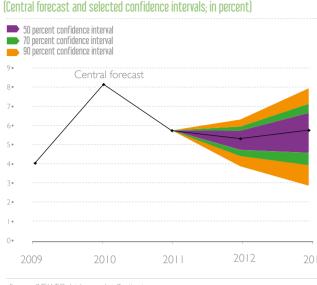
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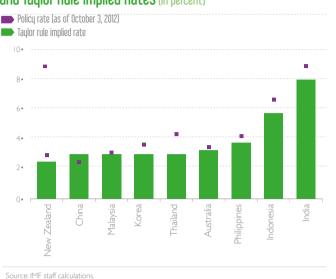
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### Figure 6. Real GDP Growth



### Figure 7. Selected Asia: Nominal Policy Rates and Taylor Rule Implied Rates (In percent)



Sources: IMF, WEO database and staff estimates.

A hard landing in China remains a low probability, but high-impact risk for the region. China has become an important engine of growth for the region and a hard landing would have a significant impact on regional economies and beyond. As highlighted in our 2012 spillover report on China, each one percentage-point decline of investment growth in China would lower GDP growth by more than half of a percentage point over four quarters in those economies with the closest regional supply chain links to China, including Korea, Malaysia, and Taiwan Province of China.

# Policymakers need to support stable noninflationary growth, maintain financial stability, and lay the foundations for sustained and shared prosperity over the medium term.

The current monetary stances are generally more accommodative than is suggested by Taylor rule estimates, and thus provide appropriate insurance against downside risks (Figure 7). Moreover, compared with rate cuts after the Lehman shock, there is still ample policy space in most Asia-Pacific economies to cut nominal rates in the event of a severe global downturn.

The balance of risks, and therefore the scope for monetary policy action differs substantially across Asian economies. In Japan, the most recent monetary easing measures are welcome and should help support economic growth and an exit from deflation.

However, further easing of monetary policy may be needed to accelerate achievement of the Bank of Japan's inflation goal of I percent, and would likely be more effective in the context of a broad structural reforms and fiscal adjustment.

Elsewhere in the Asia-Pacific region, should activity fail to pick up as projected, further easing may be warranted where inflation is well within comfort zones and monetary stances are closer to neutral (e.g., Korean and Malaysia). On the other hand, still-high inflation (e.g., India and Vietnam), and strong past or recent credit growth (e.g., Indonesia) may limit the room for policy maneuver in some economies, although credit growth has generally slowed in recent months and has remained broadly commensurate with nominal GDP growth.

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Treatment of bacterial diseases, e.g. lyme disease Visit us at Arab Health 2013 at the booth Arabian Ethicals In order to address financial stability concerns, macroprudential measures, like efforts in China to rein in real estate lending and local government-financing vehicles, remain an essential complement to monetary policy. Similarly, food price related risks warrant careful monitoring and may limit monetary policy space should they manifest themselves as second-round effects.

The pace of fiscal consolidation will also need to be calibrated depending on country circumstances. Higher structural deficits than before the crisis imply the need to rebuild fiscal space in many Asian economies (with the notable exceptions of China and Korea). Expected improvements in structural fiscal balances across most of the region for 2013 are therefore welcome under the baseline projection. However, automatic stabilizers should be allowed to play as a first line of defense if economic activity were to weaken further. And because such stabilizers remain generally small in emerging Asia (Figure 8), countries with more fiscal space should also set up and be ready to implement discretionary plans if global economic conditions were to take a turn for the worse.

# (Correlation between output gaps and cyclical fiscal balances)

Vietnam Australia

Igapore

China

nilippines

Korea

apan

Figure 8. Automatic Stabilizers

Malaysia

Source: IMF staff estimates.



Fiscal reforms will also remain a policy priority to achieve greater economic resilience and inclusive growth, including by reorienting government budgets toward investments in social safety nets and critical infrastructure. Strengthening and improving the efficiency of government revenues will also remain a priority. This is the case in many low-income countries, to finance growing development-spending needs, but also in Japan where the recent Diet approval of a doubling of the consumption tax rate by 2015 is a crucial first step toward a credible longer-term fiscal strategy to achieve public debt sustainability.

Sustained high rates of growth over the medium term cannot be taken for granted, and the magnitude of the recent slowdown in some large Asian economies has raised concerns that it might not be just cyclical. Structural reforms have played a key role in strengthening Asia's economic fundamentals and allowing the region to lead the global recovery and weather the global economic turbulence of recent years. However, many Asian economies have now reached a development stage that exposes them to the risk of falling into the "middle income trap," which is the phenomenon of hitherto rapidly growing economies stagnating at middle-income levels and failing to graduate into the ranks of high-income countries. To sustain economic growth over the medium term and make growth more inclusive, a diverse policy agenda will be required in different parts of Asia, ranging from economic rebalancing to strengthening the sources of private sector-led investment, to reforms in goods and labor markets, and meeting the opportunities and challenges from rapid demographic change. Collective action will also help, particularly the maintaining and furthering of strong regional trade integration.

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



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# CGF: concentrate growth factor from tissue regeneration

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

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

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

CGF, like other platelet concentrates, is isolated from blood samples through a simple and standardized separation protocol, which is per-



formed by a specific centrifuge device (Medifuge MF200, Silfradent srl, Forlì, Italy) without the addition of exogenous substances.

A study made in the "Laboratory of Organ and Tissue Regeneration", headed by Professor Luigi F. Rodella of the Section of Human Anatomy, Department of Biomedical Sciences and Biotechnologies of the Uni-

versity of Brescia and published in the international journal "Microscopy Research and Technique" has highlighted some of its main features: the CGF consists of an organic matrix rich in fibrin that is able to "trap" a greater amount of growth factors (TGF-B1 and VEGF); moreover, it contains CD34 positive stem cells, which are known to be recruited from blood to injured tissue and play a role in vascular maintenance, neovascularisation and angiogenesis.<sup>1</sup> In addition, an other study underlined the need to establish a standardized protocol for preparing CGF (also said PRF-Platelet Rich Fibrin) membranes for clinical use.<sup>2</sup>

Form a clinical point of view, some recent studies about the use of CGF in maxillofacial surgery showed the efficacy of CGF in guided bone regeneration before dental implant placement.<sup>3-5</sup> In particular, there are satisfying results about the use of CGF as alternative to bone substitutes for sinus augmentation.<sup>4,5</sup>

However, its features make it suitable for its use, alone or with other biomaterials, in other fields where tissue regeneration and remodelling is required. To date, the research continue and is



addressed to evaluate "in vitro" the ability of CGF of stimulate cellular proliferation and to test the efficacy of CGF in different clinical applications ranging from oral surgery, dermatology and cosmetic surgery.

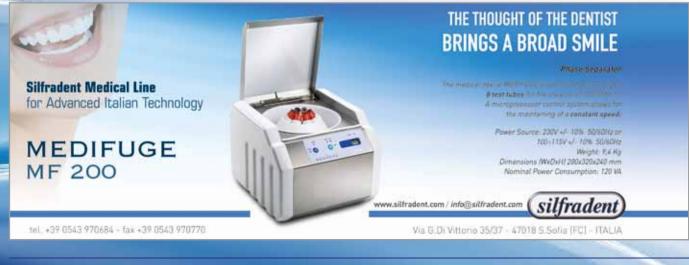
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