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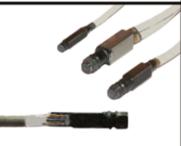
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"We view the healthcare market in the MENA region to be one of the most attractive markets for healthcare investments in the world..."

16



Focus on Medical Devices Market in China

"Chinese medical market is estimated to grow by 13% in 2011, one of the fastest in the world and the 11th largest at US\$16 billion in 2010..."

20-29



IMF Seeking to Curb Tension, Risks in World Economy

"The IMF, seeking to reduce continued tensions and economic uncertainty around the world, has published a new work program that highlights its strategic focus for coming months..."

36-39



Contents

TECHNOLOGY UPDATE

4 Learn more about our Advertiser's Products

EXHIBITION PRE & POST SHOW REPORTS

16 Arab Health 2012

18 Medical Fair Asia 2012

FOCUS

20 Focus on Medical Devices Market in China: Social and Economic Outlook

INTERNATIONAL MARKET & TRENDS

30 Opportunities for the Medical Market in Saudi Arabia

AT A GLANCE

36 IMF Seeking to Curb Tension, Risks in World Economy

CERTIFICATES & REGULATIONS

40 Registration of Imported Medical Devices in China



Japan, Moving Forward after the disaster

"In the wake of Japan's worst-recorded earthquake, tsunami, and a nuclear emergency, the Japanese people and government face a massive reconstruction effort..."

53-57



Children in East Asia & Pacific Region face multiple deprivations

"The study entitled *Child Poverty in East Asia and the Pacific: Deprivations and Disparities* noted that family poverty often affects children most directly through their access to shelter, food, water, sanitation, education, health and information..."

59

44 Medical Device Regulation in Saudi Arabia

46 BUSINESS OPPORTUNITIES

HOT TOPIC

Japan, Moving Forward after the disaster

KALEIDOSCOPE

- 58 Massive Humanitarian Response to Somalia famine has saved children's lives
- 59 Children in East Asia & Pacific region face multiple deprivations

60 EXHIBITION & CONGRESS CALENDAR

64 WHAT'S NEXT

Cover page

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

-Amedo Smart Tracking Solutions GmbH48
- Applied Optical Technologies P. Ltd34
- Axel Srl51
- BMI Biomedical International Srl31
- Bosung Meditech Co. Ltd47
-CalzeG.T.S.r.l47
- Chifa Sp. z o.o
- DURICO C&T, Inc41
- Ekom Spol s r.o40
-Euroclinic S.r.l64
-General Project S.r.l50

- GPC Medical Ltd61
- H. Buschkuhl GmbH38
- Hironic
- IAE Spa33
- IMD Generators Srl48
- Innovative Endoscopy Components, LLC
Inside Front Cover
-IntegrityLifeSciences35
- J-Standard Dent57
- Menfis Biomedica Srl51
-MercuryMedical43

Metaltronica Srl	4
Multi Radiance Medical Inc	1
Operon S.A	5
Phoenix Diagnostics Inc	5
Rexmed Industries Co. Ltd	39
Seiler Instrument Mfg, Co., Inc	2
· Sterylab Srl	4
Tinget - Pujiang Optoelectronic Technology Co., Ltd	4
· YSY Medical	



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Healthcare industry remains competitive in the region

Commentary by Simon Page, Managing Director, Life Sciences, Informa Exhibitions.

How does Has Arab Health retain its competitive edge year-on-year?

Retaining our competitive edge in the market and appealing to our target audience has meant that it has been necessary to stay up-todate with market fluctuations and to identify new trends in the MENA healthcare industry.

We view the healthcare market in the MENA region to be one of the most attractive markets for healthcare investments in the

world. The healthcare market has experienced stellar growth over the last decade and is projected to maintain its growth momentum driven by a multitude of factors including demographic growth, high and expanding medical needs, more active investments by governments and private sector in the healthcare market, development of social welfare systems, introduction of private insurance market, increased healthcare regulation, introduction of compulsory health insurance in a number of countries: to name a few.

By acknowledging the current trends in the market and identifying the niche opportunities available for our exhibitors, Arab Health continues to be the preferred platform for our customers to market their products, garner intelligence, debate industry issues and network with each other.

For many years Arab Health was venue bound selling out year on year with no room to expand. In 2010 that all changed with the addition of the new Sheikh Saeed halls to the existing space at the Dubai International Convention and Exhibition Centre.

These four new state-of-the art halls added over 25,000sgm of exhibition space allowing Arab Health to grow by more than 20 per cent in size from previous years allowing Arab Health to firmly cement its position as one of the foremost healthcare trade events in the world.

Year on year Arab Health continues to build on our conference portfolio offering a scientific and educational platform that comprises the world's largest multi-track series of conferences. Each year we assess the specific requirements for the region and we develop our conferences specifically to cater for the delegates who attend our conferences. Last year we saw the launch of four new conferences and this year the Arab Health Congress will be further enhanced with the addition of Biomedical Engineering, Medical Ethics, Medical Education, Psychiatry and Wound Care conferences bringing the total number of CME accredited conference to 17.

Remaining competitive also means rewarding achievement which is why we host the annual Arab Health Innovation & Achievement Awards that recognise the outstanding achievements of individuals, departments, teams or an organisation that have contributed to the growth and development of the Middle East Healthcare Industry. The 2012 Arab Health Awards winners will be announced on the 24 January, 2012 at a gala awards dinner at the Intercontinental Hotel, Dubai Festival City, Dubai.

Have you seen any particular shift in target audience demographic over the same period?

The audience at Arab Health changes and develops subtly as the healthcare market changes. We are seeing greater percentages of international visitors to the event as Arab Health becomes the exhibition of choice for healthcare dealers, distributors, purchasers and specifiers across the globe. The large majority of visitors are from outside the UAE. In particular we have seen growth in the attendance from China, India, other Asian countries as well as central Europe. We have also seen an increasing number of visitors interested in emerging healthcare sectors such as e-health from across the globe.

Are you optimistic about the future of the healthcare exhibitions industry?

In a report released by KFH Research Limited about the future status of the healthcare sector in the GCC, experts expect the healthcare market to triple within the coming years to reach USD \$55 billion in 2020, a year-on-year growth of 9%.

This offers proof of the immense potential for all aspects of medical provisioning in the region, namely in the transfer of know-how, training, the building of clinics and hospitals and in the import and export of pharmaceutical products and medical supplies.

The report also indicates that the estimated value of forthcoming GCC healthcare projects will reach USD \$10 billion alone. The rapid growth in population rate and the increment of expenditure per capita in the GCC on healthcare is considered to be the most important factors.

These factors have caused governments in the region to pay closer attention to meeting the healthcare needs in their respective countries by putting in place plans for several large-scale projects in the sector as well as reforming rules and regulations governing the industry with the view of attracting more private sector investment in the space.

Healthcare exhibitions such as Arab Health will continue to be a major platform for companies looking to expand their presence into this niche market.

The Arab Health Exhibition & Congress takes place from 23 - 26 January, 2012, at the Dubai International Convention and Exhibitions Centre.

For more information about Arab Health. visit www.arabhealthonline.com.





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Asia's most prominent medical trade fair returns to Singapore with a 50% expansion in floor space

The 9th edition of Asia's most significant medical and health exhibition, MEDICAL FAIR ASIA, returns even bigger and better to Suntec Singapore from 12 to 14 September 2012. With a show floor extended by some 50% to occupy all three halls on level six of the convention centre, MEDICAL FAIR ASIA 2012 – the biggest edition yet since its debut in 1997 – will showcase an international lineup of leading medical and health care players from around the world. Focused on equipment and supplies for the hospital, diagnostic, pharmaceutical, medical and rehabilitation sectors, all three halls will bring together new and in-

novative technologies, solutions, products and services from around the world, in line with current and future demographic trends, medical and health care challenges and the next wave of healthcare modernisation. As part of the international series of medical trade shows presented by the Messe Düsseldorf Group, MEDICAL FAIR ASIA, organised by Messe Düsseldorf Asia, has established itself as the region's most effective business forum for medical and health care manufacturers and suppliers to feature their products and services to procurers, healthcare givers, practitioners and professionals, and decision makers.

Leading forum for medical and health care sectors.

With a history that spans more than a decade, the biennial exhibition has grown exponentially over the years. The last edition of MEDICAL FAIR ASIA held in 2010 set a new record in the number of attendees and exhibiting companies as it attracted more than 7,000 quality trade visitors, and 475 companies from 31 countries, of which 80% came from overseas.

Next year, MEDICAL FAIR ASIA is expected to attract strong participation from some 500 exhibitors from 35 countries and an attendance of 10,000 trade visitors from across ASEAN and the Asia Pacific region. It is also anticipated to draw participation from various national groups such as Austria, China, France, Germany, Japan, Malaysia, Singapore, South Korea and Taiwan, further underpinning the global relevance of the exhibition.

Growing medical device market

Raising the bar and providing a platform for the medical technology segment, 2012 will see the addition of MEDICAL MANUFACTURING ASIA to Messe Düsseldorf Asia's portfolio. Colocated with MEDICAL FAIR ASIA 2012, the exhibition is jointly organised by the Singapore Precision Engineering & Tooling Association (SPETA).

MEDICAL MANUFACTURING ASIA comes at a time when the Asia Pacific medical device market is expected to account for 25% of global market share and reach US\$62.3 billion in revenue by 2012. The colocated exhibitions offer synergistic opportunities for specialists sourcing diversified solutions. With the expansion of the show floor and the concurrently held exhibition, this further reinforces MEDICAL FAIR ASIA as the region's most prominent medical and health care equipment and supplies sourcing platform.

"The increasingly rising participation and attendance at MEDICAL FAIR ASIA with record numbers at the last edition in 2010, coupled with the

booming medical and health care industry in Asia, is a clear indication of the growing need for a trade fair specifically dedicated to Asia's medical and health care sectors. It is also testament to the exhibition's role and position as a meeting place for all medical and health care professionals in Asia and beyond," says Gernot Ringling, Managing Director, Messe Düsseldorf Asia

Boom in the healthcare market

The unprecedented growth of the Southeast Asian healthcare market due to the ever increasing awareness and benefits of quality healthcare, upward trend of medical tourism, rising ageing population, higher life expectancies, and economic development have given rise to a booming medical and health care sector particularly in medical devices and equipment. The demand for improved medical and health care products and services is expected to ignite the growth of a global market for medical equipment and supplies, currently valued at US\$273 billion. Countries in the region, particularly Singapore, Thailand and Malaysia are already making headway as they take advantage of the boom in the global healthcare market. At present, Southeast Asia records the highest private health expenditure of any region in the world, at 63.1% of total health expenditures.

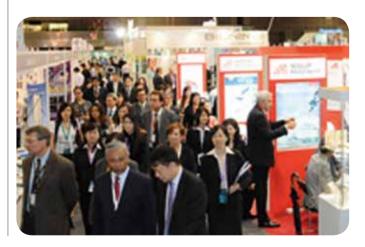
Set against this impressive backdrop, major ASEAN nations are boosting their healthcare spending in order to expand access to treatment, modernise their medical systems and furnish more advanced services to both local and foreign patients, and to cater to the silver industry.

This emergent market creates opportunities for enterprising companies across the entire health care ecosystem planning to penetrate the ASEAN region.

Space applications are now open for MEDICAL FAIR ASIA 2012 and MEDICAL MANUFACTURING ASIA 2012. For more information on the exhibitions, please visit www.medicalfairasia.com / www.medmanufacturingasia.com or contact:

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Email: zarina@mda.com.sg teresa@mda.com.sg

Exhibitor contact:
Michelle Leong
Tel: (65) 6332 9682
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48.6% **Figures** US\$ 5,183 US\$ 6.9 trillion 53.8% US \$1.58 of GDP trillion Currency Imports Renminbi US\$1.39 (yuan) trillion

Population

About 49.7% of these are urban residents, a considerable share that increased by I3% compared to 2000.

Eastern China is the most populated region of the country, inhabited by 38% of the Chinese population. Central and Western China account both for roughly 27%, while the remaining 8% live in the North-eastern region. The Eastern region is attracting migratory

inflows as shown by the 2.4% increase of inhabitants on 2000, while all

the other regions registered drops between 0.2% and 1.1%.

hina is the most populous country in the world, with 1.34 billion inhabitants that makes 19% of the global population.

China is the most populous country in the world, with 1.34 billion inhabitants that makes 19% of the global population.

The 5 most populated provinces are Guangdong, Shandong, Henan, Sichuan and Jiangsu. During the last decade about 117 million persons moved from their town or place of origin, as a consequence of the rapid shift of rural labour force to non-agricultural activities and the faster economic development in urban areas attracting migrant workers.

Ageing Population

China's population is ageing fast, owing to low fertility and rising life expectancy. As a consequence of about three decades of one-child policy the fertility rate fell under 1.5, below the sustainable rate for a country like China that also experiences a low proportion of girls amongst total births, due to a history of gender discrimination. The ratio of the elderly to those aged 15-46 is projected to grow four-fold by 2050, and even higher in rural areas.

Economy

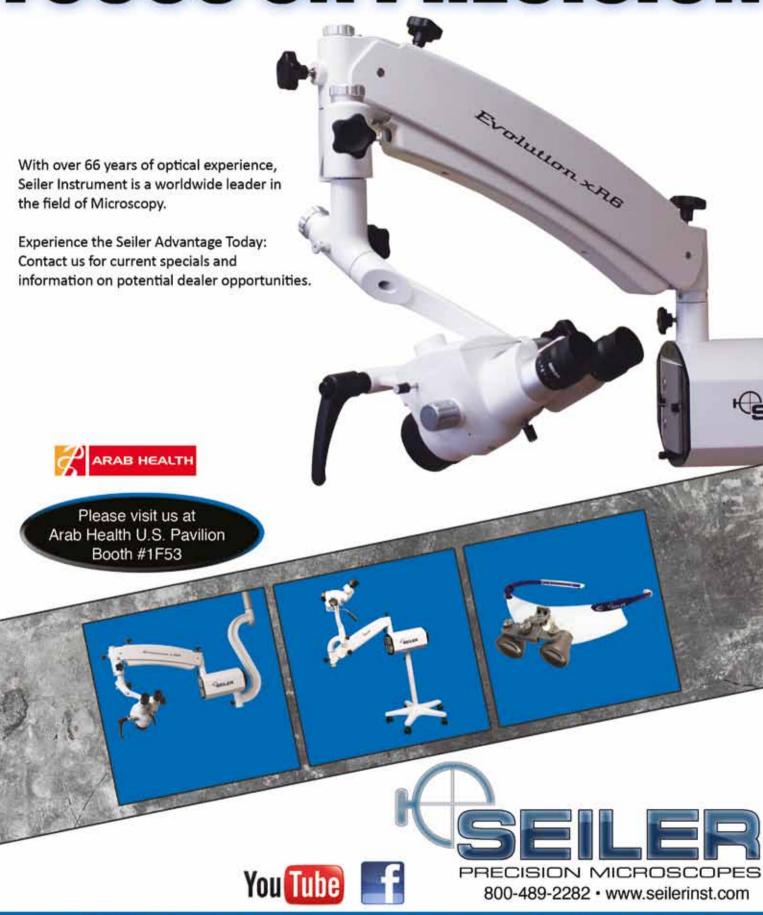
Achievements and challenges

Since the economic liberalization in 1978, and even more after WTO accession in 2001, China has become the fastest growing major economy in the world, with an annual average GDP growth of about 10% in the last decade, and expected to continue at a slightly reduced rate of 9% in the next five years. It is worth mentioning that China alone contributed to 30% of global growth in 2010.

China's GDP is the second-largest in the world after US, although such ranking not mirrored by GDP per capita (91st out of 183 countries). Foreign exchange reserves are the world's largest and China is also the world's 3rd largest recipient of FDI and 6th largest outward investor. The impressive growth registered by Chinese economy relied mainly on low cost manufacturing activities and undervalued exchange rate.

It is worth mentioning that China alone contributed to 30% of global growth in 2010.

FOCUS ON PRECISION



trategic sectors such as energy and heavy industry are still under State control, but the private enterprise has expanded to about half of Chinese national output.

Many social indicators have improved along with economic development: millions of people were lifted out of poverty bringing the share of population below poverty line of US\$1 per day to 10% (from 64% in 1978), while life expectancy has increased to 73 years. More than 93% of the population is literate and urban unemployment officially declined to 4%, although a more realistic overall figure may be around 10%. Urban incomes have nearly doubled in the last decade and wages rose on average 13% a year between 1978 and 2009.

However, such rate might be an overestimate, as it covers mostly State-owned or State-linked companies, while other institutional surveys show that the growth rate for average annual salaries in the private sector is about 6%.

China's middle-class (with annual income of at least US\$17,000) has overcome 100 million in 2011, while super-rich individuals (over US\$1.5 million) are estimated to be 825,000. China ranks second in the world for both number of billionaires and market for luxury goods. As a counterpart to such achievements, it must be noticed that China paid a high price for its record scores, in terms of human, environmental and social costs.

China has 20 of the world's 30 most polluted cities and although the country is the largest wind energy provider in the world, and renewable energies are planned to constitute 30% of total energy production by 2050, the degree of air and water pollution is extensive and worrying. On the social side, economic growth has however been very imbalanced and uneven, with huge gaps running among different regions and rural versus urban areas.

While the heavily urbanised eastern coastal regions concentrate almost all the investment and resulting development, inner provinces and countryside were left behind and have been only recently targeted by government programs aimed at rising their infrastructure and wealth.

Domestic consumption and more inclusive growth

Being an export-led economy dependent on global demand, China was hit considerably by the 2009 contraction in world trade, but thanks to a massive fiscal stimulus, its recovery was faster and stronger than many other developing economies. The latest five-year plan is focused on rising per capita income and boosting domestic consumption in an effort to modernize the economy and counteract the crisis of the main traditional recipients of Chinese exports, US and Europe. A positive signal in this direction is the increased share of consumption in economic growth from 25% in 1995 - 2000 to 56% in the last five years.

However, some downward trends show signs that Chinese economy is cooling. For instance, China's quarterly GDP growth fell to 9.1% in October 2011, down from 9.5% in the previous quarter. A huge speculative property bubble and high inflation, added to local governments indebtedness, are making it questionable for China to be able to sustain such massive growth as registered in the last decade, and with the same economic model. Even if the government has already implemented measures targeting food inflation, excess bank lending and currency appreciation, the need for a decided shift towards a more domestically demand led growth remains a priority. It is also essential that growth becomes more inclusive also by strengthening the social security system.

In this regard, one of the major challenges are the inequalities between the rights of locally born residents and migrants, and within official and unofficial migrants, as regards pensions, healthcare, education and social security in general.

For instance, workers with a local urban residence permit (hukou) enjoy considerable privileges over migrant workers, who earn 50% more than unofficial migrants. However, only a few migrant workers can obtain a "hukou" as the required conditions (such as a high income, house ownership) are usually out of reach.



Unofficial migrants in urban areas are estimated to be 39% of the urban labour force.

Most of them work in the private sector without contracts and minimum guarantees. Although labour and contract law is in theory strict, only 20% of urban employees hold such a contract, mainly in civil service or State owned enterprises.

Some of these issues have been addressed in the last five years with a rise in public health financing and the implementation of new medical insurance programmes for previously uncovered people and expansion of pensions coverage to rural areas, but there is still much to be done.

Healthcare

The Ministry of Health (MOH) is in charge of drafting laws, regulations, and policies related to public health, overseeing the administration of Traditional Chinese Medicine, and for administering China's rural health insurance system. Provincial Health Bureaus are the administrative authority for hospitals in the area. These bureaus determine the distribution of major medical device purchases.

Along with a system of national, provincial, and local facilities, the MOH regulates a network of industrial and state enterprise hospitals. China has had 20,291 hospitals as of 2009, and a total 907,249 medical facilities.

Chinese hospitals are divided into non profit units enjoying preferential tax policies and for-profit units, including Sino-foreign joint ventures and clinics, that may set their own prices, treat self-funded patients and must pay taxes. Joint ventures use advanced equipment and technology and offer broader, higher quality services than local hospitals.

Investments in medical facilities has long been focused in urban areas, where the number of hospitals grew by about 25% between 2000 and 2008 along with the number of beds. However, China needs to catch up with the global policy shift towards increased focus on primary care. Patients often consider primary care doctors as less qualified and turn to hospitals. Tier I facilities, in fact, account for only 10% of outpatient visits and 5% of inpatient visits, while the remaining is on tier II and III. Many people prefer to seek treatment at hospitals instead of local health centres for even minor complaints.

Health system problems

China's healthcare system began to fall apart in the 1980s when many State owned companies that used to provide healthcare coverage to their employees were privatised. Since 1980s, the percentage of personal income people spend out-of-pocket on healthcare has doubled.

During the 90s healthcare was profit driven and heavily reliant on the sale of expensive pharmaceuticals to balance public underinvestment, but this approach produced huge disparities, with access severely limited in rural areas and even major urban centres struggling with adequate funding and care. Many patients were even turned away from hospitals because they couldn't pay.

Inequities are more evident in rural China, where more than half population lives and incomes are lowest. As part of its reform plans, the government plans to build a clinic in every village but it is difficult to attract qualified medical staff to remote areas that most urgently need medical care. In poorest provinces many villagers haven't seen a doctor ever, women often give birth at home, medications are priced out of reach and facilities are inadequate.

However, problems in major cities are great as well: the best facilities and doctors are available, but only at large money expense. Emergency patients are often told that operations can't be performed without payment of expensive fees and many cities have not extended coverage to employees without cover.

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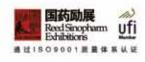




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Healthcare Reform

The government has implemented a vast plan to reform the healthcare system to be rolled out in a period that started in 2009 and will continue to the projected goal of universal healthcare access in 2020, with an investment for the period 2009-2011 of US\$130 billion.

The main points of the reform are:

Insurance Reform

- Expanding urban coverage of basic medical security (UBMI), covering individuals employed by institutions and including retirees and migrants in urban cities, and a voluntary enrolment to Urban Cooperative Medica Scheme (UCMS) at a lower premium to include children, students, seniors and the unemployed.
- New Rural Cooperative Medical Scheme (NRCMS) enrolment is conducted voluntarily and measured on a per family unit basis, with provision that the younger generation may opt out of the program at a later stage. Funding provided by government subsidies under NRCMS will increase to RMB120 per person.
- The two massive health insurance programmes implemented have brought the share of population with some form of medical insurance from 10% to 90%, and are expected to cover 550 million urban residents and 800 million rural residents by 2012. Rural patients who previously had no insurance can now afford medical care, as the government covers part of the costs.

Expanding the network of primary and secondary care facilities and professionals

Facilities	Existing	2New (2009-2011)
Hospitals	220,291	+2000
Health Service Centre	27,308	+17,100
for Community		
Rural health centres	39,627	+29,000 (+5,000 renov.)
Outpatient Departments	7,639	n/a
Clinics	174,809	n/a
Total	907,249	+53,000

Source: Ministry of Health, National Development and Reform Commission

- Focus on establishing 2,000 provincial level hospitals including TCM hospitals, complete 29,000 township clinics and renovate or expand 5,000 clinics in remote villages; construction of 2,400 urban community health centers in disadvantaged areas
- Strengthening healthcare workers: training to health professionals 360,000 for township health centers, 160,000 for urban community health centers and 1.37 million for village clinics
- Rural posting for doctors to receive intermediate/senior titles and graduates encouraged
- Reforming compensation mechanism: operational costs will be covered by government subsidies and through services charging; healthcare staff will be compensated as that of public institutions
- Push for initial diagnosis at community health center and dual referral system to relieve tier II and III hospitals.

Construct Preliminary National Essential Medicine System

- Drug reimbursements by hospitals and pharmacies
- Catalogue necessary drugs produced and distributed under government control and supervision starting in 2009; covered by medical insurance
- Basic Public Health Services

Some improvements were registered in the health status of the population and the government has broadened its efforts to expand health insurance coverage in urban and rural areas, which has led to an increased demand for services. The government is also encouraging the development of private healthcare for wealthier individuals who can afford to pay more.

The Market for Medical Equipment

Chinese medical market is estimated to grow by 13% in 2011, one of the fastest in the world and the 11th largest at US\$16 billion in 2010. Domestic medical facilities are increasingly importing foreign devices, as shown by the growth of imports from Us\$4.4 billion in 2006 to US\$7.2 billion in 2008 according to China Association for Medical Devices Industry (CADMI), and expected to rise by 12-15% annually in the next few years boosted by investment in hospital and health facilities envisaged by reforms. It must be noticed that according to several sources, leading multinational companies account for 90% of high-end market and among the industry's top 10 manufacturers, seven are foreign invested firms or joint ventures. Hospitals are the main buyer of foreign high-tech equipment and products, but since domestic medical device companies are improving quality, they begin to compete in medium-level segments, which is dominated by local production. There are currently over 12,600 medical device manufacturers, in South China alone there are I I,000, producing about US\$27 billion value equipment annually.

Chinese medical market is estimated to grow by 13% in 2011, one of the fastest in the world and the 11th largest at US\$16 billion in 2010.

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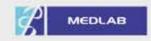
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A special mention deserves the **Rehabilitation market**:

- 155 million elderly people, 12% of total population, to increase by 6 million annually by 2020
- About 83 million disabled persons with 80% of those requiring assistive devices; 65 million cannot live without assistive devices.
- By 2015, at least 70 million assistive devices need to be supplied, and rehabilitation facilities for 39 million people to be installed
- Gap of 5 million nursing beds for the elderly
- Enough purchasing capacity but few quality products
- Chinese government provides more support for the elderly and physically challenged population.
- To facilitate the importation of imported products, China plans to eliminate import duties for qualifying products.
- China announced in April 2009 that it will promote barrier-free environment for the disabled in 100 cities by the year 2010, including technologies such as Braille, sign language, special communication facilities. Standardized community rehabilitation services will be carried out nationwide in 80% of urban districts and 70% of counties.

Market Size of Medical Devices Industry Sub-Segments:



- Dental (Dental Implants): 2%
- Orthopaedics (Implants, Supports): I 3%
- Consumables (Syringes, Catheters): 20%
- Diagnostic imaging (X-ray Machines, MRI): 39%
- Other (ECG, Incubators, Ventilators, Heart-Lung Machines): 27%

Source: Espicom Business Intelligence

No distributor in China has nationwide access so it is necessary to appoint many distributors.

Market entry and distribution

Main buyers consist of hospitals and urban/rural health centres. Around 160,000 medical device distributors are active in China, with concentration varying across provinces:

- Jiangsu 10%
- Shandong 9%
- Jilin, Heilongjiang 6%
- Sichuan, Beijing 5.4%
- Hubei 5%
- Zhejiang, Yunnan, Shanghai 4%

These provinces account for about half of the total number of distributors. No distributor in China has nationwide access so it is necessary to appoint many distributors.

Domestic companies have on their side business contacts and knowledge of complex local regulations, so joint ventures can give foreign companies an advantage in gaining access customers. An important thing to consider is the reimbursement list of medical insurance; if the treatment or exam involving the medical device that the company intends to market is not included, the demand for such product is not going to be high. It is crucial to get familiar with Chinese habits before starting a trade negotiation with a local partner. In this perspective, a permanent basis inside the country allows to get useful insights of the local culture and to keep up with a rapidly changing social and economic context. Whatever approach the company chooses to the Chinese market, whether by participating to exhibitions and congresses, or through direct commercial meetings and introductions, it is important to address the critical aspects involved in the protection of intellectual property rights.

The demand for foreign products is growing as well but both sales and distribution on the Chinese market pose serious challenges to intellectual property rights protection.

Consumer profile

Some specific considerations on the Chinese middle class are necessary, given its importance for companies looking with interest to the possibilities offered by such a large base of consumers.

According to a report by Boston Consulting Group, when examining a specific market segment and growth potential in China, official statistics on GDP per capita and population may not correlate well with targeted income groups. It is misleading, for instance, to assume that all rural areas are poor: by 2020, average income of top 200 rural areas will exceed average income of bottom 300 urban areas. As smaller to medium companies may find it quite difficult to expand across different regions, they need to choose which province to target in the first phase. In this analysis, not only the total size of targeted income segment but also density, favourable where such segments are concentrated in few locations, impacts on efficacy of market penetration.

Intellectual property rights

The demand for foreign products is growing as well but both sales and distribution on the Chinese market pose serious challenges to intellectual property rights protection.

It is important to carefully consider which information will be made available by exhibiting or advertising products, as disseminating too detailed information might potentially favour the creation of illegal copies. Information and product displays need to be limited to the necessary extent and only after related intellectual property has been identified and adequately protected. Before a company enters the Chinese market, it has to register patents and trademarks and it is advisable to register copyrights too. Costs are limited even by taking into account the support given by a specialised agency.

Sources

International Monetary Fund - www.imf.org
National Bureau of Statistics - www.stats.gov.cn

MOH- www.moh.gov.cn

US Commercial Service - www.buyusa.gov

China Medical Device Industry - www.camdi.org.ch

Espicom - www.espicom.com

Italian Trade Commission - Government Agency - www.uibm.com

Opportunities for the Medical Market in Saudi Arabia

General Figures

MOH budget as % of Gov. Expenditure:

6.2

GDP per capita

\$14,550

GDP growth (2011 forecast):

Population:

27,1 million (2011 est.)

Per capita MOH expenditure:

27

Economy overview

he Kingdom of Saudi Arabia, with an area of about 2,150,000 square km, is the largest country of the Arabian Peninsula. It is the world's leading oil exporter and the largest economy in the Middle East, accounting for 70% of the Gulf Cooperation Council's GDP. Oil accounts for 85% of exports and 75% of government revenues. As regards imports, machinery and equipment account for about 30%, transportation equipment for 18% and food and agricultural products for 15%.

The oil sector alone has contributed on average to 54% of GDP over the last five years and although the Saudi government keeps investing in oil refining and natural gas production, it also aims at reducing dependence on the oil sector and creating more jobs for the growing national labour market.

Four new Economic Cities are planned to be developed in different locations of the country over the next 20 years, housing about 5 million inhabitants and contributing around US\$150 billion to annual GDP. Initial investments are estimated at around US\$70bn.

Healthcare provision

Saudi Arabia is a welfare state providing free healthcare services to all citizens in public facilities, under the responsibility of the Ministry of Health. Public healthcare services are delivered through a network of primary healthcare centres (2,037) located in both large cities and small towns throughout the country, 244 general hospitals and 56 specialized hospitals. Additionally, other independent government agencies run 39 hospitals and they provide services in primary, secondary and tertiary healthcare facilities for their workers and their families. In extreme cases, some of these agencies provide specialized healthcare services such as cancer therapies to the general public. The Ministry of Health is establishing primary health centres as the single point of access for all patients and increasing their number to create a referral system that helps decreasing delays in public hospitals. According to the Ninth Five-Year Development Plan, 117 new hospitals, 750 primary health care centres and 400 emergency centres will be established by 2014.

In 2010, the Saudi Government allocated US\$16.3 billion for healthcare and social affairs, a 17% increase on 2009, and in the 2011 budget allocated some US\$18.3 billion.



- Mobile radiographic units for bedside examinations;
- Mobile C-arms for orthopaedics-cardiology-surgery and interventional radiology;
- Radiographic systems, for routine and specialized radiography;
- R/F systems, for all radiographic and fluoroscopic examinations with advanced Digital Imaging Systems;
- Mammographic Units
- Endoral and Panoramic dental units

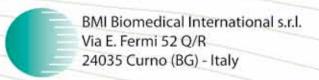
BMI Biomedical can also provide components such as monoblocs, generators, Toshiba X-ray / Image Intensifier tubes for the manufacturing industry

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Private sector

Government funding covers most of the demand for healthcare capital and operating expenditures, while private sector spending accounts for 25% of the total. Private facilities are mainly located in the urban centres. The private sector runs 125 hospitals and provides 21.2% of total beds. Despite incentives to investment, the private share in the provision of healthcare services is still low compared to the public sector.

24.8% of private hospitals is in leddah, followed by Riyadh (21.6%).

These two regions together account for:

- about half of the total number of private beds
- 55% of the total number of private polyclinics (758 in Riyadh, 312 in leddah)
- 68.7% of the total number of private clincs (48 in Riyadh, 101 in Jeddah)

In order to face the growing demand, healthcare is one of the key sectors targeted by the privatization program envisaged by Saudi government. The Ministry of Health plans to reduce its role as healthcare

funder and to become a regulatory institution for private healthcare services. The introduction of the Cooperative Insurance Act has created a large market for insurance as all employers are now required to provide private health insurance, initially to non-Saudis, but eventually to cover all employees. As reported by the organizers of the "Saudi Health Insurance Conference", around 34 insurance companies are operating in Saudi Arabia, witnessing rapid growth; by 2014, total insurance premiums are projected to be worth US\$11.8 billion.

Primary Healthcare Centers, 2009

Services available		Regions with highest %			
54%	Qunfudah	90			
31%	Makkah	51			
73%	Makkah	97			
	54% 31%	54% Qunfudah 31% Makkah			

Source: MOH Report 1430

Private sector, 2009

Facility	Total no.	Physicians	Dentists	In Riyadh	In Jeddah
Hospitals	125	16,767	3,826	24.8%	21.6%
Polyclinics	1,944			39%	16%
Clinics	217	220	55	22.1%	46.5%
Company clinics	147	161		-	

Source: MOH Report 1430

Health workforce, 2009

Health professional	Total	Density per	% Saudi	PHC	МОН	Private
		10,000				
Physicians (incl. dentists)	55,284	21.8	23.1	6,853	25,832	16,767
Dentists	7,410	2.9	23.6	1,222	2,551	3,881
Nurses	110,858	43.7	32.3	16,620	63,297	23,308
Pharmacists	14,943	5.9	51.1		1,654	10,553
Allied health personnel	59,618	23.5	66.3	7,917	32,360	9,833

Source: MOH Report 1430

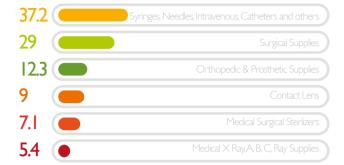
Medical Market: profile and prospects

In 2010, the Saudi Government allocated US\$16.3 billion for healthcare and social affairs, a 17% increase on 2009, and in the 2011 budget allocated some US\$18.3 billion. Spending increase is influenced by the expansion of chronic and lifestyle diseases such as obesity (affecting 29% of adult males and 37% of adult females), cardiovascular diseases (accounting for 25% of deaths), diabetes (3.5 million people affected) ad cancer (7,000 new cases per annum). These conditions are creating strong need for healthcare services in the Kingdom.

Along with a general increase of the total population (est. 30 million by 2016), the rising group of persons aged 65 and above is expected to double by 2020. These are additional factors that will drive the future demand for diagnostic and monitoring devices, particularly diabetes and cardiovascular medical devices.

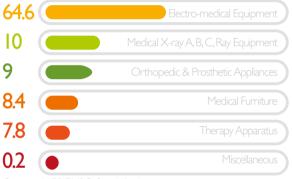
Increased investment in healthcare infrastructure with new hospitals and clinics established all across the Kingdom and the growth of health insurance has boosted the medical device market that peaked to \$790 million in 2009. The market relies abundantly on imports, with USA as main supplier followed by Germany and France. According to figures provided by the Saudi Food and Drug Authority, domestic medical factories are prevalently located in Riyadh (52%), followed by Jeddah (18%). Dammam (16%) and the remaining regions hosting 14% of factories. As regards the distribution network, it is composed of about 400 dealers concentrated mainly in Jeddah (40%). Another 30% of them is located in Riyadh and 20% in Dammam, with the remaining 10% scattered across the country.

% of Medical Supply Imports by Major Categories



Source: MEDEXPO Saudi Arabia

% of Medical Equipment Importers by Major Categories



Source: MEDEXPO Saudi Arabia



The pharmaceutical market has grown to \$2.7 billion in 2009 and is expected to reach \$3.5 billion by 2012, as Saudi Arabia remains the main consumer of drugs in the Middle East accounting for 65% of the total market, Pharmaceutical imports are dominated by German companies with 16.2% market share. The pharmaceutical company Pfizer has recently signed an agreement for a new manufacturing plant in King Abdullah Economic City. The projected complex is claimed to incorporate medicine manufacturing and packaging technologies in order to produce medicines for the local market and serve the growing demand in the Kingdom.

The government provides incentives to companies investing in Saudi Arabia, and the improved business environment (the country holds the 11th position in the World Bank "Doing Business" rank) helps attracting foreign investors.

The government provides incentives to companies investing in Saudi Arabia, and the improved business environment (the country holds the I Ith position in the World Bank "Doing Business" rank) helps attracting foreign investors. The progressive liberalization of the sector will open many new opportunities to access the large Saudi Market. According to the national investment agency SAGIA, some of the factors that will boost investment in the country's health sector include:

- the number of hospital beds, expected to rise to 70,000 by 2016, and the number of hospitals from 408 to 502;

- wide unmet demand in medical education, research, facilities, provision and reimbursement:
- moves towards a compulsory, insurance-based system that will extend to all Saudis, with some 6 million people already covered by private insurance:
- high incidence of major disease categories including diabetes, heart disease, and congenital disorders;
- private hospitals, pharmaceutical companies and medical device manufacturers seeking international partners;
- the need for modernization of primary healthcare provision (supported by government's shift to preventative care) and for a comprehensive national health information system;
- the need for multidisciplinary hospitals and specialized centres for cardiology, diabetes and more complex disciplines such as oncology and organ transplants (due to capacity saturation, long waiting periods and limited availability of specialists at public hospitals);
- growing number of outpatient facilities offering ambulatory care, ambulatory surgical capacity and diagnostic imaging centres as hospitals are working over-capacity;
- entirely privately funded healthcare system in the new Economic Cities, with high-quality services and infrastructure. They will be at the forefront in implementing e-health.

Sources:

MEDEXPO Saudi Arabia (17 - 20 June 2012, Jeddah)

www.medexposaudi.com

Ministry of Health - www.moh.gov.sa

"Health Care Investment Opportunities", Saudi Arabian General Investment Authority (SAGIA) - www.sagia.gov.sa

SFDA Saudi Food and Drug Authority - www.sfda.gov.sa

Arabian Business – www.arabianbusiness.com





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- Still-high vulnerabilities, growth, job creation among top priorities
- Heightened risks prompt new attention to global financial safety net
- IMF to give more attention to economic, financial interconnections

The IMF, seeking to reduce continued tensions and economic uncertainty around the world, has published a new work program that highlights its strategic focus for coming months.

he IMF, seeking to reduce continued tensions and economic uncertainty around the world, has published a new work program that highlights its strategic focus for coming months.

Among the top priorities will be providing insightful analysis and policy advice to address vulnerabilities and rekindle growth and job creation. The IMF will seek to strengthen the institution's lending instruments to help reduce these vulnerabilities, and prevent and resolve crises. Work will also focus more attention on the interconnections in the global economy, particularly via the financial sector.

Other priority initiatives include advancing capital flows work and enhancing support for low-income countries. Many of these issues will be high on the agenda for leaders of the Group of Twenty (G-20) leading advanced and emerging market economies as they meet in Cannesat the end of November:

In an interview with IMF Survey online, Reza Moghadam, head of the IMF's Strategy, Policy, and Review Department, discusses the key areas of work for the next six months.

IMF Survey online: IMF Managing Director Christine Lagarde has said that the global economy has entered a dangerous new phase. How will this influence the IMF's work?

Moghadam: The global economy is going through a very difficult period, and that is certainly reflected in our work program. There are continuing concerns about financial market volatility, weaker growth prospects, and fiscal and financial vulnerabilities. At the 2011 Annual Meetings, the International Monetary and Financial Committee (IMFC), the IMF's policy-setting body, asked us to work on resolving these tensions, focusing on advice and policy initiatives to address both immediate threats and longer-term concerns. Euro zone leaders have since taken important steps in the right direction at their recent summit. However, the challenges facing the euro area, and the global economy more generally, require continued efforts.

Addressing vulnerabilities and rekindling growth and job creation are our top priorities. In that context, we will look closely at the nexus between fiscal policy and employment growth, lessons from the initial crisis response, as well as booms and busts and their links with credit cycles.

Our financial support to member countries is another critical way we help reduce vulnerabilities. We currently have Fund arrangements with more than 50 countries, with total commitments of roughly \$270 billion. Looking ahead, it will also be critical for us to make sure that we have the right lending instruments, and that they are adequately resourced. We will be working on these issues in the weeks and months ahead.

IMF Survey online: Given the particularly difficult task that policymakers face, how is the IMF refocusing its policy advice to best support member countries?

Moghadam: The IMF's policy analysis and advice to individual countries—what we call bilateral surveillance—remains as important as even Indeed, this dialogue with member countries is a key strength of the Fund, and discussions will focus closely on the vulnerabilities that I mentioned earlier.

That said, the global crisis has also made it very clear that economies are closely interlinked: problems in one part of the globe can spread rapidly to others. We are trying to incorporate this reality in our analysis, for instance, with spillover reports for the five systemically important economies and work on interconnectedness to help shape our policy advice. The ultimate aim is for our bilateral and multilateral surveillance to complement and reinforce one another, especially when countries face common challenges.

IMF Survey online: Recent developments have put the spotlight on the IMF's role in the global financial safety net. Should we expect further reforms to the IMF's lending toolkit?

Moghadam: Both the IMFC and the G-20 have stressed the importance of an effective global safety net, particularly given the heightened risks in today's global economy. To this end, the work program emphasizes two ongoing endeavors: (i) further reforming the IMF's lending toolkit to make it more flexible and broaden its reach to better deal with rapidly evolving crises, and (ii) broadening the scope for using the IMF's nonconcessional emergency assistance.

As a first step, the IMF's Executive Board will soon review the experience with the Flexible Credit Line and the Precautionary Credit Line. This review will inform discussion of proposals to strengthen the IMF's existing toolkit, focusing on enhancing our existing nonconcessional lending instruments. Early next year, the Board will also conduct a major review of program conditionality to evaluate its design and implementation, along with program outcomes, for IMF-supported programs approved since 2002.

The IMF needs to have adequate resources to give confidence and this is something both our membership and G-20 finance ministers, at their

meeting in Paris in October, have emphasized. Indeed this issue will also be discussed by G-20 Leaders at their meeting in Cannes at the end of November. The IMF's Board will soon review the adequacy of Fund resources. It is also essential that the IMF's member countries complete, as soon as possible, the steps needed to implement the quota increase agreed in 2010.

IMF Survey online: Low-income countries are also more exposed to risks from global economic problems. What action is the IMF taking to help them confront these challenges?

Moghadam: Low-income countries have fared better in the last crisis than in previous ones. Thanks to improved domestic policies, they built up buffers (such as higher reserves and lower debt) that provided policy space during the crisis. However, those buffers have not been fully rebuilt since the crisis, and in light of uncertain prospects for donor assistance, low-income countries remain more exposed to global shocks.

For this reason, the IMF is focusing more closely on the vulnerabilities low-income countries face, and what policies are needed to address them. The first of these detailed "vulnerability exercises", focuses on assessing the impact of global growth and commodity price shocks. Together with the World Bank, we will also review the framework we use for assessing debt sustainability in low-income countries. This will be followed in early 2012 by a thorough review of the policy on debt limits introduced in December 2009.

In keeping with the added attention to effective financial sector surveillance for all members, we will undertake work analyzing the impediments to, and potential benefits and risks from, financial sector deepening in low-income countries.

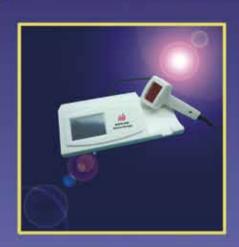
The Executive Board will also discuss a range of papers on the IMF's financial support to low-income countries, including on the Heavily Indebted Poor Countries and Multilateral Debt Relief Initiatives, and reviews of country eligibility and interest rates under the Poverty Reduction and Growth Trust.

IMF Survey online: The IMF has just completed the Triennial Surveillance Review. What changes in the focus of the IMF's work should we expect?

Moghadam: The crisis was an important catalyst in improving IMF surveillance. Initiatives like the early warning exercise or mandatory financial sector assessments for systemic economies reflect the lessons we drew from the crisis. But there are areas that need further improvement. The review called for more attention in five areas: interconnectedness, risk assessments, financial stability, external stability, and impact or traction of IMF surveillance. The legal framework for surveillance was also found to be falling short of supporting stronger and more integrated surveillance.

The Managing Director's "Action Plan" includes concrete measures to make IMF surveillance more effective, candid and evenhanded. Let me highlight just a few of the major elements: as I mentioned earlier, there will be additional coverage of spillovers and cross-country experiences, and more explicit discussion of risks in discussions with member countries. We also plan to develop a strategic plan for the IMF's financial sector surveillance and propose to assign a financial expert to each Article IV team covering a systemically important financial sector.

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IMF Survey online: Looking beyond the immediate threats to the global economy, a major goal of the IMF has been to make the international monetary system less prone to crisis. What will be the priorities for moving this line of work forward?

Moghadam: Reforming the international monetary system is a daunting task. It requires both near-term actions as well as longer-term structural changes. In the coming months, the steps we're taking to strengthen surveillance and the global safety net are important elements of a near-term response.

The current work program also calls for additional work on understanding capital flows, with a view to developing a comprehensive framework for thinking about capital flows to best promote growth and stability. Discussions are planned in two areas: the multilateral aspects of policies affecting capital flows, and capital account liberalization and management of capital outflows. These two papers are intended to complement our earlier work to examine the IMF's role regarding cross-border capital flows and on managing capital inflows. Together, these outputs—and the discussion they will engender—should provide further support for developing a comprehensive framework for thinking about capital flows to best promote growth and stability.

The Spring 2012 Global Financial Stability Report will include a chapter on the implications of fewer "risk-free assets" for global financial stability, which is particularly relevant to the functioning of the system. Of course, reforming the international monetary system has engaged generations of economists. Not only are these reforms a long-term endeavor, but the constant evolution of the global system means that we should never assume that our work is done. Surely, as the global economy climbs out of its current perilous state, there will be more questions to answer.

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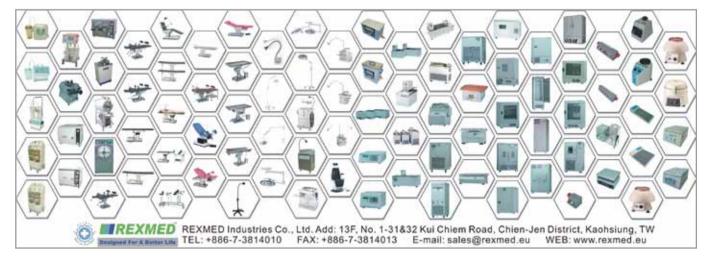
Author: IMF- International Monetary Fund
Publication: IMFS urvey Magazine

Website: www.imf.org

IMF- International Monetary Fund

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Registration of Imported Medical Devices in China

Registration of Imported Medical Devices in China

Agencies that have regulatory roles for imported medical equipment

State Food and Drug Administration (SFDA)

All imported medical devices must get a registration certificate from SFDA before being sold in China. The SFDA has a comprehensive system for medical device registration and inspection, which includes product type testing and factory audits.

General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) is responsible for certifying electrical safety for some electro-medical devices. Upon certification, products receive a "China Compulsory Certification" (CCC).

For Medical device products which fall into the category of pressure vessels, Chinese Customs requires certificates issued by the Safety Quality Licensing Office for Import Boiler and Pressure Vessels (SQLO) of the State Administration for Technical and Quality Supervision, in addition to SFDA and AOSIO certification.

Registration procedure

1. Appointing a Legal Agent and After Sales Agent

Foreign manufacturers wishing to register their medical device in China are required to appoint a Legal Agent and After Sales Agent: the Legal Agent processes the registration for the manufacturer, and must receive a letter of authorization stating that agent is the sole agent for the company's registration and that the manufacturer is responsible for the product, that will be included in the Medical Device registration application. The After Sales Agent is responsible for sales and after sale service, and must be based in China and registered with SFDA. The manufacturer must specify the after-sales agent in an authorization letter to be submitted to SFDA, together with a letter of promise from the agent. When a manufacturer wants to use more than one agent, Authorization Letters need to be issued to all the Chinese agents. If, at a later date, a manufacturer wants to change its agent(s), it must inform SFDA.

The distributor can act as Legal Agent, but as it controls device appro-

val, this involves the risk of limitation in flexibility to switch distributors. It is however essential that the Legal Agent is familiar with local regulations and technical requirements and with product's technical features, as it may be asked to answer technical questions during the testing.

2. Classification of Medical Devices

Chinese classification of medical devices (based on SFDA Order No. 15) has three risk-based classes (Class I is lowest, Class III is highest), but risk levels are different from FDA or CE so the same device could fall into a higher class in China, impacting on registration cost and time. However, medical devices in all classes need to be registered.

3. Registration Documents

The list of documents necessary to submit an Application to SFDA for Import Medical Device Registration Certificate (IMDRC) differs from Class I to Class II-III products.

All Classes:

Application Form

Available on SFDA website (www.sda.gov.cn), filled out in both Chinese and English;

Business certificate or manufacturing enterprise license

Issued by the government agency of the country of origin; copy sealed by the original issuing agency or notarized by local notarization agency;

Qualification certificate of the applicant

- Business certificate of the commissioned agency or registration certificate of the manufacturer's representative;
- •Certificate of commission given by the Manufacturer to the Legal Agent and the After-Sale Service Agent designated in China. The name of the product must be clearly indicated;

The Authorization Letters provided by the manufacturer to its Agent should be submitted to SFDA together with an acceptance letter from the local Agent with company's stamp.



Product marketing approval (original or notarized copy)

CE Mark, 510K/PMA and CFG, other countries' approval. If the product:

- Does not need marketing approval in the country of origin;
- •Is not regulated as medical device/had no specific medical device marketing approval in country of origin, and is produced specifically for China:
- •Or bears any change from the approved product, the company should provide;
- •Free sale certificate/certificate to the foreign government (notarized copy);
- Self-guarantee declaration of compliance with local regulations;

Chinese Registration Standard (Certified Copy)

Declaration of compliance with Chinese national standard (usually equal to international standard, sometimes with minor changes). ISO or IEC standards will be converted in SFDA standards. In absence of any national standard, an industry or company-specified standard may be used. Only original of the Standards sealed by manufacturer or Legal Representative (with related indication in Certificate of commission) is accepted.

All requirements must match or exceed Chinese National Standards (GB) or China's Professional Standards (YY), including Technical and Safety Requirements for Electronic Medical Devices (GB9706.1-1995 or equal to IEC60601.1:1988, Medical Electrical Equipment, Part 1) and Material Medical Devices (ISO10993:1997)

Operation Manual

Class I does not require Manual to be sealed by the manufacturer; Class II-III does.

Depending on product, it includes:

- 1. Name of Product, Manufacturer name and contacts;
- 2. Registration number and applied product standards;
- 3. Structure, performance, usage, application, contraindication, precautions, cautions and suggestions;
- 4. Interpretation of labels and marks;
- 5. Illustration of installation and operation;
- 6. Maintenance/special storage methods and length of life;
- 7. Other necessary contents specified in the Product Standards;

The manual should be in English and Chinese; translation should follow the Provisions on Instruction for Use and Labeling of Medical Devices (SFDA order No.10).

Manufacturer Certificate of Quality (original or notarized copy)

Notarized quality system certificate (such as ISO 13485, US FDA QSR or their national quality system certificate)

Self-Guarantee Declaration

Manufacturer or agent's declaration of authenticity and accuracy of data and information in the registration document, listing all materials submitted, and commitment on the Liabilities.

In addition to the above listed documents, Class II-III devices need:

Type test Report

Issued by a medical devices quality test agency recognized by the SFDA within the last year.

Some high tech medical devices can be registered before having completed testing (Test-after-Registration) under manufacturer's commitment to complete the Test at first, as the device gets into the Chinese market.

If the product fails to pass the test, the registration certificate is cancelled. Devices eligible are: C T, PET, SPECT, Extraneous Shock Wave Crusher, Color Ultrasonic Diagnostic Scanner, Large Laser Therapy Apparatus, Large X-Ray Diagnostic Equipment, Automatic Biochemical Analyzer, Cobalt 60 Therapy Unit, Gamma Knife, Medico- electronic Linear Accelerator, Simulated Positioner, MRI System.

Devices can be exempted from Type Test if:

- •Covered by domestic company's certificate (GB/T19001+YY/T0287 or GB/T19002+YY/T0288) issued SFDA recognized agency;
- Authorized in the country of origin, with company authenticated under ISO 9000 (or equivalent);
- Bear irrelevant safety/effectiveness difference with approved devices;
- They are not implantable device, or have no radioactive sources;
- •No accidents such as death or injury can be caused by malfunction;

Besides all Class I products, laboratory equipment, electrophoresis apparatus, centrifuge, ultra low temperature refrigerator, paraffin slicing/embedding machine, cell centrifuge smearing machine and full automatic dying machine are exempt.

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Clinical trial report

If the device has US, European or other national approval, the manufacturer must provide a copy of relevant clinical reports. If clinical reports weren't required in the country of origin, the manufacturer states it upon application.

Local clinical trials are required, at any rate, for:

- •Class III Implantable Device (long-term, more than 30 days), only for the initial registration in China:
- Class II or Class III products that do not have country of origin approval;
- •Local clinical trials must be performed in SFDA Approved Clinical Research Institutions (Hospitals), in at least two clinical sites. SFDA has certified ten testing laboratories as technologically competent to perform the required tests in an effort to alleviate these problems:
- •No clinical reports are required for: Class I products, IVD reagent except those for the diagnosis of hepatitis and AIDS (to have Clinical Trials in designated medical institutions); condoms, laboratory equipment, electrophoresis apparatus, centrifuge, ultra low temperature refrigerator, paraffin slicing/embedding machine, cell centrifuge smearing machine and full automatic dying machine;
- All documents must be translated in Chinese:

4. Approval and Labeling

Once the imported medical device is approved, a registration certificate valid for 4 years is issued by SFDA.

When importing medical devices into China for the first time, the agent should receive the registration certificate before applying for customs formalities. The registration number must be placed on device label, packaging and user manual. Label should be in Chinese and include registration certificate number; product features, scope of usage for the product, warnings, validity dates.

5. Issues and problems

Among the other difficulties companies face in China, there are:

- Frequent updates of SFDA regulations;
- Standard differences, delays, distribution dependency;
- · Possibility to fail license renewal, even for already registered products;
- •Since testing is done before standard validation, should standards be rejected the manufacturer must revise them and submit the dossier again;
- Communication problems;

AQSIQ "China Compulsory Certification" (CCC)

Compulsory Certification covers a variety of electro-medical devices: electrocardiographs; hemodialysis equipment; extracorporeal blood circuit for blood purification equipment; hollow fiber dialyzer; implantable cardiac pacemakers; medical x-ray diagnostic equipment; artificial heart-lung machine.

Application for CCC mark requires many technical documents, and can take 60-90 days or more. Manufacturers must submit samples to an accredited laboratory in China at additional cost.

Moreover, factory inspection by Chinese officials (at applicant's expense) and follow-up inspections by notified bodies in the country of the factory recognized by AQSIQ are required. In some cases component parts of a finished product may need CCC certification, requiring the component manufacturer to apply for CCC mark. Spare parts and replacement parts shipments may also require CCC certification, or application for an exemption.

Useful contacts:

State Food and Drug Administration - www.sfda.gov.cn

General Administration of Quality Supervision, Inspection and Quarantine - www.aqsiq.gov.cn China Quality Certification Centre - www.cqc.com.cn



Medical Device Regulation in Saudi Arabia

he Saudi Food and Drug Authority (SFDA) is developing the medical devices regulatory framework in Saudi Arabia. On 27th December 2008, SFDA issued a Medical Devices Interim Regulation, valid until approval of the medical devices comprehensive law, establishing the regulatory approach for the Saudi marketing authorisation and the post-marketing surveillance of medical devices.

According to the regulation, only medical devices that have been authorised by one of the founding members of the Global Harmonization Task Force (European Union, United States, Canada, Australia and Japan) can enter the Saudi market.

Eight Implementing Rules complete the Regulation, each of them specifying application dates of the Interim Regulation provisions. The most relevant provisions for medical manufacturers, importers and distributors are summarized below.



Implementing Rule on Establishment Registration

Local manufactures, authorised representatives, importers and distributors involved in the supply of medical devices, authorised by the SFDA, need to register their establishments with the SFDA's Medical Device National Registry (MDNR) through the SFDA's website. The registrant provides information on its role (e.g. local Manufacturer, Importer, and Distributor), the name of a responsible person, particulars of the medical devices involved (e.g. manufacturer's details, country of origin, identification code, any pre-market approval and, where applicable, post-market activities) and is assigned an Establishment National Registry Number by the SFDA.

Implementing Rule on Medical Devices Listing

Local manufacturers, authorised representatives, importers and distributors involved in the supply of SFDA authorised medical devices are required to list the devices they intend to place on the Saudi market with the SFDA's Medical Device National Registry (MDNR). Each medical device is assigned a Listing National Registry Number.

Implementing Rule on Establishment Licensing

All importers/distributors of SFDA authorised medical devices in the Saudi market must obtain an establishment license for each activity issued by the SFDA before supplying devices.

Implementing Rule on Licensing of Authorised Representatives

Any manufacturer not established in Saudi Arabia must designate an organization authorised to act on his behalf in the Kingdom. This authorised representative applies to the SFDA to obtain the establishment License.

Implementing Rule on Marketing Authorization

Manufacturers wishing to supply a medical device in Saudi Arabia must provide the SFDA with documentation that demonstrates that the device is authorised to be placed on the market in one of the GHTF Founding Member jurisdictions and that it complies with the specific Saudi requirements. SFDA issues a written marketing authorisation to the manufacturer. After 3 I st December 2011 only medical devices with an SFDA marketing authorization may be placed on the market.

The Medical Devices Sector of the SFDA (SFDA/MDS), which is responsible for the regulatory scheme, has issued a number of guidelines providing information on obligations related with the Interim Regulation and the Implementing Rules.

MDS guidelines include information on:

Authorized Representative - In order to appoint an authorised representative in Saudi Arabia, the manufacturer must prepare a written mandate allowing the representative to act on its behalf in its dealings with the SFDA and listing each medical device category or generic device group intended to be supplied to the Saudi market. If the manufacturer intends to introduce more than one category or generic device group of medical device into the market, it may designate a different authorised representative for each category or generic device group.

According to the implementing rules listed above, whereas the overseas manufacturer does not need to be registered with the SFDA, the authorised representative must obtain an Establishment Registry Number in order to apply for an establishment license, before it may act on the overseas manufacturer's behalf. The authorised representative may represent more than one manufacturer; with separate licenses for each manufacturer.

A guideline entitled Guidance for Authorised Representatives is available on the SFDA website and provides an overview of the registration and licensing process. One important requirement is to provide the SFDA with a copy of the written mandate between the overseas manufacturer and authorised representative.

Marketing authorization - Medical devices may be placed on the market and/or put into service only after the SFDA has issued the manufacturer with a written marketing authorisation.

Marketing authorization is required for:

- all medical devices, whatever their risk class;
- contact lenses for cosmetic as well as for medical purposes;
- laser surgical equipment intended for cosmetic as well as medical purposes;

Accessories of medical devices are considered as medical devices in their own right and they are therefore subject to the provisions of the Interim Regulation and to obtain marketing authorization.

This, instead, is not required for medical devices designed and constructed by health facility staff for internal use within that health facility, alone. Before an overseas manufacturer may apply, through its authorised representative, for marketing authorization for one of the medical devices it manufacturers, it must first comply with the regulatory requirements that apply to that device within one of the GHTF Founding Member jurisdictions, namely, Australia, Canada, Japan, the USA or the EU. The medical device must also comply with provisions specific to Saudi Arabia concerning labelling and conditions of supply and/or use.

The manufacturer may use the marketing authorization it has in one of the five GHTF jurisdictions as the basis of its application to the SFDA, by providing its authorised representative with the necessary information to complete the appropriate marketing authorization application form found on the SFDA website

Medical Device Listing - After a medical device has obtained marketing authorization, the manufacturer's authorised representative is required to provide the medical device listing information to the Medical Device National Registry (MDNR), before supplying the medical device to the market for the first time.

The registrant must access the electronic application form available in Section C of the MDNR and provide the Medical Device National Listing Number of the medical device it is supplying to the Saudi market.

The form must be filled out with the following information:

- a) Quantity, serial numbers or lot numbers, shipment date, and destination of the medical devices that are being supplied to the Saudi market. b) An indication that the information provided is either a new entry or an update of previously submitted information.
- c) The date when the listing information is submitted.

Furthermore, the registrant must update the data provided to the MDNR annually, or as required by the SFDA, or within 10 calendar days of the occurrence of any significant change to the relevant information.

Storage, Handling and Transport of Medical Devices - The overseas manufacturer is responsible for proper packaging, handling, storage and transportation of the medical device, taking into account the environmental conditions to be encountered both within and outside Saudi Arabia with respect to temperature, humidity, vibrations and the risk of physical damage.

The manufacturer also provides written information, both in Arabic and in English, to organisations responsible for transporting its devices, to distributors and to users, on the required transportation, handling and storage conditions while each is responsible for the device. Moreover, the manufacturer has to ensure clear packaging identification and that any individual medical device within the consignment is accompanied by all relevant documentation, such as, the instructions for installation, maintenance and use, in the language required by the Interim Regulation.

Post-Market Surveillance of Medical Devices

SFDA has established the National Center for Medical Devices Reporting (NCMDR) to record, analyze and manage medical device recalls and adverse events occurring with devices during their use. The SFDA will review adverse events reported to its NCMDR and take appropriate action to safeguard public health.

The SFDA plans to establish a mechanism to issue Field Safety Notices to medical device users and, where relevant, patients. Before issuing such a Notice, its text shall be discussed with the organisations responsible for manufacturing the device and supplying it to Saudi Arabia.

If the manufacturer confirms a malfunction or deterioration in the characteristics and/or performance of the medical device, as well as any inadequacy in the labelling or the instructions for use, and which has led, or might have led, to death or serious deterioration in the state of health of a patient, user or third person, it shall submit an adverse event report to the SFDA and agree a corrective action plan.

The manufacturer is required to label the medical devices with an unambiguous identification, such as batch code/lot number, or serial number, preceded by the word LOT or SERIAL NUMBER (or an equivalent symbol) as appropriate.

Source:

Saudi Food and Drug Authority (SFDA), "Guidance for Overseas Manufacturers" – www.sfda.gov.sa



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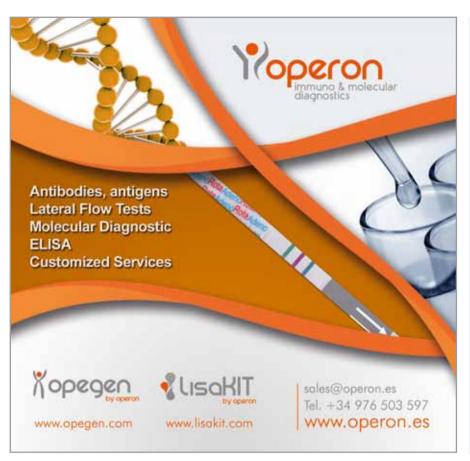
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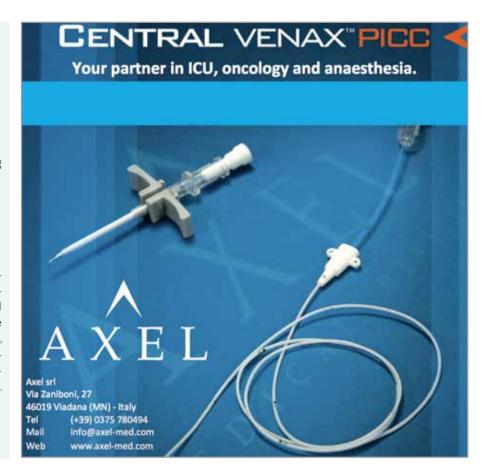


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Japan, Moving forward after the disaster

Earthquake, Tsunami and Nuclear Cris's Proves
Most Destructive Event Since World War II

wide range of economic challenges.

This included installing a new Industrial Structure Vision,

apan entered 2011 with a bold determination to confront a

promoting stronger East Asian integration, reforming the agricultural sector, and potentially entering into talks con-

cerning the Trans-Pacific Strategic Partnership.

Dynamics within Japan, however, shifted abruptly on March 11th when the nation was hit by a massive earthquake and 30-foot tsunami.

Just before 3:00 pm local time on March 11th, a massive undersea earthquake with a magnitude of 9.0 on the Richter scale struck Japan's northeastern coast, 400 kilometers from Tokyo. The earthquake generated a massive tsunami that crashed into Japan's eastern coast-line, causing severe flooding, damage to buildings, boats and cars, and a multitude of human casualties.

More than 50 aftershocks followed throughout the day, many exceeding a magnitude of 7.0.

As noted by Tokyo University Professor Naoto Sekimura nuclear fuel at the stricken Fukushima Daiichi power plant began melting just five hours after the initial earthquake. Tokyo Electric Power Company (TEPCO) has also now confirmed that fuel pellets "melted, falling to the bottom of the reactor pressure vessel at a relatively early stage after the tsunami reached the station" as well as additional details concerning the state of the nuclear power station at the time of the earthquake.

n March 12th, Japanese authorities announced that four nuclear power stations in quake-hit areas had been shutdown.

A "state of emergency" was declared at Tokyo Electric Power Company's Fukushima Dajichi Nuclear Power Station after the disaster caused cooling systems to fail at its Number I reactor. More than 3,000 residents living within 6.2 miles of the plant were evacuated. An explosion at the Fukishima plant raised fears of a meltdown, lapanese authorities mobilized over 100 thousand military

and civilian rescue personnel to begin rescue and relief efforts. More than one million households were without water, and four million buildings without power.

On March 13 Japan's nuclear safety agency announced the cooling system of a third nuclear reactor at Fukushima failed, as nuclear plant operators relentlessly fought to cool the

damaged reactors to prevent a nuclear catastrophe.

Japan's government reported that 230 thousand people had been evacuated from areas within a twelve-mile radius around the damaged Fukushima nuclear reactors.

Prime Minister Kan addressed the nation and urged the Japanese people to unite and face "the most severe crisis in the past 65 years since World War II."

Japan continues to struggle with this humanitarian and nuclear emergency, as they maintain rescue and cleanup efforts and additional information becomes known. Traces of radiation have been found in the air and in water pouring from the reactors into the ocean. Japanese officials have also encouraged a voluntary evacuation from up to 19 miles outside the Fukushima plant. On April 12th, Japan raised its assessment of the accident from 5 to the most severe 7 rating -placing the accident at the same level as the 1986 Chernobyl meltdown.

According to the National Police Agency of Japan on May 26th, the official death toll is 15,234 with 8,616 people listed as missing. Entire towns have been destroyed, and more than 130,000 placed in temporary

The Japanese government earmarked \$48.5 billion in emergency spending, as a first step to the largest reconstruction effort since World War II.

The Japanese government has estimated total damages could total 25 trillion yen.

Some observers believe this shock will ultimately transform the lapanese society- making what had been politically and socially impossible- both necessary and essential.

The Japanese people have a long tradition of emerging stronger from adversity, and it is indeed plausible to imagine crisis will create an impetus in which old demands are abandoned and vested interests overcome to create a new consensus that results in a more open and competitive economy.

Results of an Emergency Survey on the Actual Status of Industries after the Great East Japan Earthquake

Survey period: June 14 to July 1, 2011

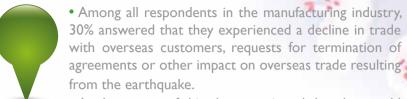
Subject to the survey: 123 companies (65 in the manufacturing industry

and 58 in the retailing and service industries)

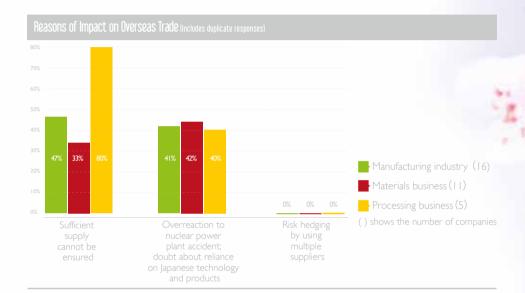
Conducted by the Japanese Ministry of Economy, Trade and Industry

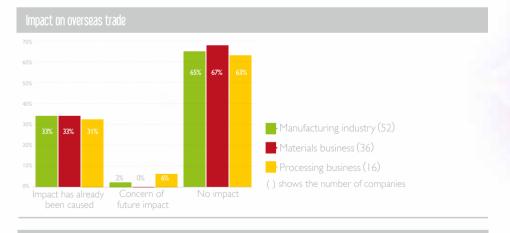


Impact on overseas trade



 As the reason of this, they mentioned that they could not ensure sufficient supply, or that overseas customers overreacted to the nuclear power plant accident.







• Among the bases for which they answered that production was below pre-earthquake levels, 70% or more will restore production to pre-earthquake levels by the end of 2011, according to the respondents.

(The emergency survey on the actual status of industries after the Great East Japan Earthquake in April asked about restoration schedules of the production bases in the disaster-affected areas such as Aomori, Iwate, Miyagi, Fukushima, Ibaraki, Tochigi and Chiba prefectures but the current survey asks about the production level at the production bases directly affected by the earthquake or tsunami.)



Japan's New Growth Strategy

In the wake of Japan's worst-recorded earthquake, tsunami, and a nuclear emergency, the Japanese people and government face a massive reconstruction effort. At this point, tireless relief efforts have focused on immediate concerns-rescue and search operations, evacuations, humanitarian aid, restoration of water delivery, and efforts to stabilize the Fukushima Daiichi nuclear reactors. The Japanese government earmarked \$48.5 billion in emergency spending, as a first step to the largest reconstruction effort since World War II.

On May 17th, Japans's cabinet adopted "The Guideline on Policy Promotion" presenting policies to revitalize Japan. These are necessary both to underpin reconstruction following the earthquake as well as to address long-term economic challenges. Additionally, the review of Japan's **New Growth Strategy** was completed this summer and concrete measures to allow implementation will be presented this year, giving further depth to Japanese efforts to reform its economy. The New Growth Strategy aims to create demand and jobs through regulatory reform and fiscal measures. The Strategy focuses on key challenges, notably climate change and population ageing, which can be turned into sources of growth.

Sustained fiscal consolidation will tend to depress economic growth from the already low potential rate of 1/2 per cent estimated by the government, making policies to support growth essential. The government's New Growth Strategy aims at accelerating real output growth to a 2% rate in the 2010s by creating a new demand through green innovation, expanded healthcare, economic integration with Asia and regional development.

Demand is to be stimulated by fiscal measures, including spending, tax measures and ensure that any spending increases are consistent with fiscal consolidation needs. In addition, reforms should not be limited to specific sectors but extended economy-wide to raise productivity. Given that the working-age population is projected to shrink by 10% by 2020, achieving the 2% average annual rate of the past decade. Priorities include promoting entrepreneurship and business start-ups by reducing the cost of creating new firms and strengthening competition policy and innovation. Jump-starting the venture business sector and following through on the planned privatization of Japan Post could also help foster private-sector dynamism.

Summary of recommendations for Japan's New Growth Strategy

Improving the overall framework of the Strategy

- Carefully monitor the fiscal implications of the Strategy to ensure its coherence and consistency with the Fiscal Management Strategy and the needs of prolonged fiscal consolidation.
- Focus on accelerating regulatory reform, particularly in services, to encourage private investment.
- Promote entrepreneurship and a more business-friendly environment, particularly by reducing the administrative burden on start-ups.
- Strengthen competition policy by increasing fines on violators of the Anti-Monopoly Act (AMA) and reduce exemptions from the AMA, including the special treatments of SMEs.

Creating New Demand

Green Growth

- Set a price on carbon emissions by introducing market-based instruments, preferably a mandatory and comprehensive cap-and-trade ETS, thereby providing a clear price signal to encourage green-growth investment.
- Make a greater use of environmentally-related taxes, particularly by introducing a carbon tax in areas not covered by the ETS, while ensuring the predictability and credibility of the tax framework.
- Encourage the development of renewable energy resources by removing non-economic barriers and creating predictable and transparent support framework. The best option would be an electricity certificate system, with incentives that decrease over time.
- Phase out inefficient fossil fuel subsidies in line with the G20 initiative in order to ensure an appropriate price for carbon.



Healthcare Reform

- Shorten the drug and medical device lag by reducing the cost of clinical trials in Japan, accepting more overseas results and ensuring the reimbursement levels are appropriate.
- Expand mixed billing to make treatments not ye t covered by public health insurance more affordable.
- Promote the shift of long-term care away from hospitals toward more appropriate institutions and home-based care using the fee schedule and closer monitoring of the classification of patients in hospitals.

Asian economic integration

- Accelerate the negotiation of comprehensive Economic Partnership Agreements with major trading partners and participate the Trans Pacific Partnerships.
- Scale back the high level of agricultural protection and shift its composition away from price support towards direct support to farmers to facilitate regional economic integration.
- Improve climate for FDI inflows by further liberalizing trade, lowering barriers to investment and ownership, accelerating reforms of administrative procedures and relaxing labour regulations.
- Liberalise controls on immigration to allow more foreign students and highly-skilled workers in Japan.

Regional Development

- Encourage use of Special Zones for Structural Reform, focusing on nationwide regulatory reform and ensure that any new special zones result in significant net benefit for the whole country.
- Allow local governments more autonomy and provide them with greater financial resources to promote regional development, including the creation of innovation clusters.

Reform in the financial sector

- Promote the supply of risk money, such as venture capital, for R&D and innovative business start-ups through policy measures to stimulate this market, which is relatively inactive in Japan.
- Scale back the size of public financial institutions, thereby reducing the flow of savings to the public sector and enhancing the availability of funds for venture business and new start-ups.
- Follow through on the privatization of Japan Post.
- Reduce credit guarantees and relax the government's policy of encouraging financial institutions to increase lending to SMEs, with the economy recovery.

Education

- · Increase public spending in education.
- Promote internationalization by increasing the number of foreign students.
- Expand public loans for tertiary education to cover a higher share of students.
- · Create vocational qualifications that are recognized by firms.
- Enhance co-operation between university research and industry.

Sources:

JETRO- "Japan faces Challenges of Earthquake, Tsunami and Nuclear Disaster"

METI- "The Second Emergency Survey on the Actual Status of Industries after the Great East Japan Earthquake"

Organisation for Economic Co-operation and Development-"OECD Economic Surveys Japan"

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Massive humanitarian response to Somalia famine has saved children's lives

Tens of thousands of Somali children's lives remain at risk; continued major support required for 2012.

ollowing the release of the latest survey findings from the Food Security and Nutrition Analysis Unit (FSNAU) in Somalia, UNICEF welcomes the news of a decrease in the number of famine zones across south Somalia.



"Thanks to the strong support from donors around the world since famine was declared in July, thousands of children's lives have been saved" said UNICEF's Representative to Somalia, Sikander Khan. According to the FSNAU's latest findings, areas in Middle Shabelle and among displaced populations in Afgoye and Mogadishu remain in famine with previous famine-affected areas - Bay, Bakool and Lower Shabelle - downgraded to Emergency levels. However, while the global acute malnutrition and crude death rates have declined in many areas, malnutrition rates continue to remain above the famine threshold levels in a large part of southern Somalia. Child death rates also remain above crisis levels in several areas.

Furthermore, large-scale disease outbreaks likely to peak during and immediately after the current rainy season and the approaching long hungry season from March to July continue to make children extremely vulnerable to death and disease over the coming months. In total, four million people remain in need of life-saving assistance.

"Let's make no mistake about this ongoing situation, children's lives are still in imminent danger. The combination of malnutrition, killer diseases and escalating conflict continues to make it a matter of life and death for tens of thousands of children with no respite for them for the majority of 2012," said Khan.

The generous support from donors has enabled UNICEF to massively scale up its emergency assistance to the most vulnerable children and families. To-date, around one million people have benefitted from nutrition assistance, including 135,000 severely malnourished children, 1.2 million children have received emergency measles vaccinations, 1.4 million people have access to UNICEF-supplied health care facilities, and 1.8 million people have access to safe water, among other interventions. In addition, with its current resources and 120 partners across Somalia, UNICEF is continuing to work to expand its emergency programme to reach more children in need in the days and weeks ahead.

To sustain and further expand its response, UNICEF now urgently reauires \$62 million by the end of November to meet all identified needs for 2011 and keep its pipeline of life-saving nutrition and health supplies open in early 2012. To ensure the possibility of eliminating famine in the existing three areas and minimize the risk of slipping into famine in all other emergency areas, UNICEF requires nearly \$300 million for its multi-sectoral response throughout 2012.

"We now call on the continued generosity of all of our donors and friends to provide the sustained support the children of Somalia require to make it out of this crisis. We must stay the course, continuing to do everything in our power to give Somalia's children their right to survive and make sure famine never happens again" noted Khan.

For more information about UNICEF and its work visit: www.unicef.org Follow us on Twitter and Facebook

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Children in East Asia & Pacific region face multiple deprivations

A

new UNICEF study analysing child poverty in East Asia and the Pacific emphasizes that poverty affects children in vastly different ways than adults. As a result, policy makers need to look beyond family income indicators to gain a more complete picture of poverty and the deprivations children face.

The study entitled "Child Poverty in East Asia and the Pacific: Deprivations and Disparities" noted that family poverty often affects children most directly through their access to shelter, food, water, sanitation, education, health and information. When a child is deprived of one or more of these essential services, their experience of poverty deepens.

Analysing the situation of children living in seven East Asia and Pacific countries with a child population over 93 million, the report found over 30 million suffered from at least one form of severe deprivation, such as the inability to go to school, or access basic health care, safe drinking water, a sanitary toilet or adequate nutrition – and more than 13 million suffered from two or more forms of severe deprivation. "The study demonstrates that income gains, including in middle income countries in the region, have not necessarily translated into gains for all children," said Mahesh Patel, UNICEF Regional Advisor for Social Policy. "Any national equity and disparity reduction policy must start with child poverty reduction at its centre."

The report reviews child poverty studies carried out in Cambodia, Lao PDR, Mongolia, the Philippines, Thailand, Vanuatu and VietNam from 2007 to 2010. "The thorough analysis presented in these national studies will help countries target programmes and policies to better reach the most vulnerable in society and to use resources most efficiently," said Anupama Rao Singh, UNICEF Regional Director for East Asia and the Pacific.

The seven Asia-Pacific countries were among 53 worldwide that participated in UNICEF's Global Study on Child Poverty and Disparity, which draws attention to the daily deprivations suffered by children and their negative impact on national development. In Lao PDR, for example, while 38 per cent of children are assessed as income poor, as many as 75 per cent are assessed as living in poverty based on this broader – and increasingly recognized – measure of child poverty. In VietNam, children from ethnic minority groups are 11 times more likely to suffer from multiple severe deprivations than children from ethnic majority groups - a pattern found in many other countries.

In Vanuatu, nearly one in five children suffers from severe health deprivation. The report also underlines that much more needs to be done to reduce the disparities that impede the development of large numbers of children in East Asia and the Pacific. Inequity is rampant, with income inequality either remaining stagnant or increasing in all seven countries despite significant GDP growth over much of the last decade.

Deprivations and disparities faced by children must feature prominently in national development and poverty alleviation plans in the region and inform how resources are allocated. Child-sensitive social protection policies that address the needs of the most vulnerable children will also be essential to reducing the deprivations children face in the region.

Gaps between rural and urban areas, different ethnic groups, geographic areas, and households headed by well-educated versus poorly educated adults were among the most notable disparities across the

seven countries. "Clearly the challenge now facing us in East Asia and the Pacific is to address the additional dimensions of child poverty revealed in this study, building on, but going beyond the foundation of economic growth in the region," Rao Singh said.

The report also revealed the following trends:

Rural versus urban - child poverty was 30 per cent higher in rural Cambodia than in urban areas, 60 per cent higher in rural Thailand, 130 per cent higher in rural Philippines and 180 per cent higher in rural VietNam;

Geographic disparities – sub-national disparities within countries are,



in some instances, more pronounced than the disparities between lower- and middle-income countries in the region— for example, the number of children suffering from severe deprivation in VietNam was over 6 times higher in the north-west region than the Red River Delta; and 50 per cent higher in southern Thailand than the North;

Disparities among ethnic minorities - disproportionately high levels of poverty and deprivation are evident among some ethnic minority children. This is an issue in almost all seven countries surveyed in the region. For example, the number of severely deprived ethnic minority children was about 60 per cent higher than the number of severely deprived children from dominant ethnic groups in both Lao PDR and Mongolia, 9 times as large in the Philippines and nearly 15 times larger in Thailand; Education of household head- severe deprivation more than doubled in households where the household head had only a primary-school education or less, compared to households where the household head had secondary or higher education;

Family size - the incidence of severe deprivation in Mongolia and VietNam almost doubled in households with more than seven members, compared to those with four or fewer. In Thailand, the incidence more than tripled under these conditions.

Source: www.unicef.org



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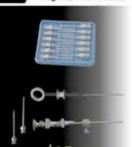


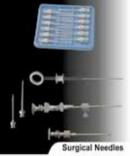






















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