

France, Germany suspend some drug approvals over Indian data

REUTERS, Frankfurt/London/Paris/Mumbai

Regulators in France, Germany, Belgium and Luxembourg are suspending the marketing approval of 25 generic drugs due to concerns over the quality of data from clinical trials conducted by India's GVK Biosciences, French watchdog ANSM said on Friday.

The quality of Indian pharmaceuticals has come under fire this year, with regulators in Europe and the United States citing problems ranging from data manipulation to sanitation and banning the import of certain products from several firms.

"This decision is taken out of precaution. No element at this stage has led to establish a true risk for human health or a lack of efficacy of these drugs," ANSM said on its website.

All of the drugs being suspended, several of which are made by Mylan and Abbott, have brand name equivalents that can be used instead, so patients will not have to interrupt their treatment, it added.

ANSM and Germany's Federal Institute for Drugs and Medical Devices (BfArM) said they were investigating the drug approvals based on clinical trials meant to show that these generic drugs were equivalent to the original branded versions conducted by GVK Bio



REUTERS/FILE

A medical representative (C) talks to a chemist at a market in Pune, India.

between 2008 and 2014.

ANSM said it had alerted European authorities after it inspected GVK Bio's site in Hyderabad, India, and found "anomalies" in the way electrocardiograms (ECG) were monitored during the bioequivalence studies.

It said the inspection raised serious concerns over whether the company's studies complied with good clinical practices.

GVK Bio's CEO Manni Kantipudi disputed the French watchdog's findings and said ECGs were not an important component of the drug efficacy.

ANSM concluded GVK Bio, which conducts clinical research for domestic and foreign drugmakers, manipulated the ECGs without taking into account the company's views, he said.

"We have agreed to redo the studies, I'm fine with that, but don't say that there was gross manipulation of the ECGs," Kantipudi told Reuters. He said the company had received board approval to spend \$5.7-\$6.5 million for new studies.

The European Medicines Agency (EMA) separately released a statement saying it would "issue a recommendation on whether the

marketing authorisations of the concerned medicines should be maintained, varied, suspended or withdrawn across the EU". That recommendation is expected in January 2015.

The German watchdog said it was investigating 176 approvals given to 28 drugmakers. It did not name the drugs or companies affected.

BfArM said it was ordering drugmakers whose approvals were found to have been based on data from GVK trials to stop distributing the concerned drugs until they could provide data from new studies.

ANSM said several drugmakers - it did not identify them - had already offered to carry out new studies which, if positive, could allow the drugs on the market again.

GVK Bio's Kantipudi said the company has started conducting new studies for five to six of its clients. About 35 of the company's 400 clients have been affected by the European regulator's move, he said.

He said the US Food and Drug Administration inspected its Hyderabad plant in June, after the French regulator's audit, and was satisfied with the ECG-related data. No other regulator had contacted the company since then, he added.



PARAMOUNT

Anita Haque, chairman of Paramount Textile, presides over the eighth annual general meeting of the company at Spectra Convention Centre in Dhaka yesterday. The company announced 15 percent stock dividends for 2013-14.

Australian economy takes hit as rate cut calls grow

AFP, Sydney

Pressure is building on Australia's central bank to cut interest rates from their record lows as growth in the resources-driven economy, already faltering on the back of China's slowdown, takes a further hit, analysts say.

The Reserve Bank of Australia (RBA) has repeatedly said it will continue to maintain a "period of stability in interest rates", but softening GDP growth figures last week sparked a flurry of economists forecasting further monetary policy easing.

That would take the cash rate below 2.5 percent, where it has been for 16 months.

"The GDP read... is creating a very dark shadow over the state of the Australian economy with income growth now in recession," IG markets strategist Evan Lucas said.

The data showed the economy expanded

by just 0.3 percent in the third-quarter, far below consensus estimates of 0.7 percent, to take the annual growth rate to a below-trend 2.7 percent. "The pressure on growth in 2015 is ratcheting up as key commodities remain in bear markets and if housing cools, this will only accelerate," added Lucas.

The slowdown in China, Australia's largest trading partner, is already weighing on the resources sector and hurting the wider economy. Continuing fears about the health of the world's second-largest economy, which helped fuel Australia's unprecedented mining investment boom, has been reflected in the local dollar's high sensitivity to fluctuating Chinese data.

Just last week, the exchange rate slumped to a fresh four-year low after weak manufacturing figures raised concerns about China's growth outlook.

China 2015 GDP target in focus as stimulus expectations heat up

AFP, Beijing

China is poised to cut its growth target for the first time in three years and ramp up stimulus as the economy comes under increasing downward pressure, analysts say ahead of a key policymakers' conference expected this week.

President Xi Jinping and other top leaders are trying to put China's increasingly affluent consumers at the centre of the world's second-largest economy, rather than investment and exports, and are ready to tolerate slower expansion in GDP to achieve more sustainable growth.

But how much lower is the question, with China's economy assailed on multiple fronts including a deflating property bubble, high debt levels, and the threat of deflation hovering in the background.

Economists will be looking for clues in next year's gross domestic product (GDP) growth target, which is likely to be decided at the annual Central Economic Work Conference.

The gathering -- which is not announced in advance -- is expected this week, although its conclusions will probably not be formally unveiled until March.

Separately, main monthly economic statistics are due this week, with analysts expecting weakening industrial production growth and chronically low inflation.

The closely watched economic conference brings together key officials to decide policy for the coming year, with topics expected to include monetary policy, the consumer price index (CPI) target, and further economic reforms.

"We expect the government to lower its 2015 economic targets for GDP growth to 7.0 percent from 7.5 percent in 2014 and CPI inflation to 3.0 percent from 3.5 percent," Nomura economists wrote.

"We believe the government will need to ease policy further -- even to meet a lower GDP growth target -- due mainly to strong headwinds from the property market correction, severe overcapacity in upstream industries and high local government debt."

Reliance Industries, Pemex to explore oil, gas opportunities in Mexico

REUTERS, Mumbai

Reliance Industries Ltd said on Friday it has entered a pact with Mexico's national oil company Petroleos Mexicanos (Pemex) to explore potential upstream oil and gas business opportunities in that country.

The deal comes as Mexico, the world's tenth-largest crude producer, is implementing sweeping reform of the energy sector that was approved earlier this year and that ended Pemex's decades-long monopoly.

Mexico's energy regulator last month said it seeks to lure over \$50 billion in investment through 2018 to stem long-sliding crude production. Current production in Mexico is around 2.35 million barrels per day.

Pemex and Reliance, controlled by India's richest man, Mukesh Ambani, will also explore international markets for "value added opportunities", the Indian energy conglomerate said in a statement.

Mexico's Pemex has been trying to expand its presence in India and other markets beyond neighbouring United States. The Mexican oil giant has said it sees India and China as future growth markets for crude.

Pemex signed an agreement in September with ONGC Videsh Ltd, the overseas business unit of India's state-run Oil and Natural Gas Corporation Ltd, to explore opportunities in Mexico's hydrocarbon sector.



BANK ASIA

Rume A Hossain, chairman of the executive committee of Bank Asia, opens the bank's agent banking booth at Oachkhali in Hatia, Noakhali recently. Md Arfan Ali, deputy managing director, was also present.



RAPPORT BANGLADESH

M Mosharraf Hossain, chairman of Rapport Bangladesh, receives a gold medal and a crest of honour from Akbar Ali Khan, former caretaker government adviser, at a programme, organised by the Commitment Culture Academy at Sonargaon Hotel in Dhaka recently.



ADN TELECOM

Asif Mahmood, chairman of ADN Telecom Ltd, attends the 11th annual general meeting of the company at Lakeshore Hotel in Dhaka yesterday. AKM Shafiul Azam, independent director, was also present.

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- ❖ LAST DATE OF APPLICATION: DECEMBER 24, 2014 before 5:00pm.

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Bangladesh Telecommunications



দেশ ও মানুষের সেবার

Company Limited Job Vacancy

Bangladesh Telecommunications Company Ltd. (BTCL) is a state-owned company that provides telecommunications services (PSTN), IGW, ICX, IIG, ISP etc.) throughout the country, invites application from bonafide citizens of Bangladesh to fill up the following position for its Head Quarter at Dhaka.

Name of Position: Managing Director

The Managing Director is the Chief Executive of the Company. He is responsible to lead a team comprising about 10,000 staff members including a large number of qualified professionals. He is responsible for overall management, e.g., administration, corporate planning, business development and ensuring the compliances of laws, rules and regulations and for good governance including development of setup, rules, regulations and systems and legal functions of the organisation. He is also responsible for supervision of all technical, financial, welfare aspects, negotiating project financing issues with donors/development partners and listing the company in the stock exchange(s) etc.

Required Academic Qualification: The candidate must have graduation in Engineering (Electrical/Electrical & Electronic/Telecommunication) from any recognised university. Any relevant higher qualification (MBA, MS, PhD etc.) or academic qualification on legal affairs would be an added advantage. The candidate must have at least two 1st divisions/classes or equivalent grade in academic record with no 3rd division/class at any stage.

Required Experience: Working experience of the candidate shall be minimum 25 (twenty-five) years in different managerial levels in telecommunications sector (in govt/semi-govt/autonomous/private organisation) with at least 5 (five) years experience in policy/decision making (with a proven track record). Experience may be relaxed for suitable candidate.

Age Limit: Age limit should preferably be in between 50 (fifty) and 60 (sixty) years as on 15 December 2014. Age may be relaxed in case of exceptionally qualified deserving candidates.

Remuneration/Compensation Package: Basic salary per month Taka 100,000.00 (one lac) only. The company will provide residential accommodation. Other fringe benefits will be provided as per company rule.

Nature of Service: The service shall be on contract basis. The contract period of the service may be for 3 (three) years which will be determined by BoD of BTCL.

Selection process: Only the short-listed candidates will be called for interviews. Interested candidate may apply along with complete CV, two (2) passport size recent photographs, attested photocopies of all educational and experience certificates. The application must be accompanied with valid National Identity Card. Application should be addressed to the Chairman, BTCL and reach the Director (Recruitment and Training), BTCL, Tejogajog Bhaban, 37/E, Eskaton Garden, Dhaka-1000 on or before 24 December, 2014 within 5:00pm.

A search committee formed by the Board of Directors will select the Managing Director from the competent candidates.

Director (Recruitment & Training)
BTCL

GD-4580