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PHARMACEUTICAL SECTOR DEVELOPMENTS

Brazil Reaches Accord with Abbott on Kaletra

The government announced on July 8 that it had reached an agreement with the US pharmaceutical firm Abbot Laboratories and as a result was dropping its threat to break Abbott's patent on the anti-AIDS drug Kaletra.

According to the Health Ministry, Abbott agreed to lower the price of Kaletra in Brazil and will also freeze the drug's price for six years. The ministry said that Abbott agreed to transfer voluntarily the technology for Kaletra's production to the state-owned laboratory Formanguinhos. Production by the government firm would start in 2009, the ministry said, but this was denied by Abbott which said in a statement that Abbott will "start transferring technology in 2009…but Brazil will not be able to manufacture the drug before the patent expires" in 2015.

The ministry did not state what the new unit price of Kaletra would be but in previous negotiations with Abbott the government had insisted that the price be lowered from its current level of US$1.17 per pill to US$0.68.

Abbott also declined to disclose financial terms of the agreement. It said in its statement that the agreement doesn't set a per-pill price for the drug. Instead, the price will be based on volume sales in Brazil, according to Abbott.

``The agreement accomplishes Abbott's objectives of helping Brazil expand patient access to Kaletra while preserving the company's intellectual property rights, which Abbott was not willing to negotiate,'' the statement said.

The ministry stated that the price reduction would permit a savings of US$18 million in 2006 and US$259 million over the next six years for the government's anti-AIDS program which provides the AIDS cocktail free of charge to patients.

In March, the Health Ministry threatened to break the patents of Kaletra and two other anti-AIDS drugs manufactured by Merck Sharp & Dohme and Gilead Science Inc. The three were given a time limit to accept the government's demand that they agree to what is called voluntary licensing for the HIV anti-retrovirus medications. If they did not, the government said it would adopt compulsory licensing which would amount to breaking their patents.

On June 24, President Luiz Inácio Lula da Silva signed a document authorizing the Health Ministry to break the patent on Kaletra after talks with Abbott failed to make progress. The US firm, however, was given until July 7 to agree to lower the price of the medication and avoid the loss of its patent.

Health Ministry officials said that talks are still continuing with Merck Sharp & Dohme and Gilead but warned that if they do not agree to the government's demands, their patents will be broken. If the government goes through with these threats, this would mark the first time that Brazil has broken a pharmaceutical patent.

For the past eight years, Brazil has been threatening to break the patents on drugs used in the AIDS cocktail. This has been interpreted as a strategy to force the manufacturers of these drugs to lower their prices for the government's purchases.

This year, however, the pressure on multinational pharmaceutical firms has grown because of the rising costs of imported drugs used in the government's program. At present, these imports are consuming 80 percent of the program's budget and the total will reach 90 percent this year. Expenditures for Kaletra alone have soared from US$35 million in 2002 to a projected US$91.6 million this year as more patients have begun taking the drug.

The much praised Brazilian AIDS treatment program was initiated in 1997. At present, 151,000 persons are receiving this free treatment at an annual cost to the government of US$200 million. The program is credited with holding the number of infected Brazilians in the range of 600,000.

Costa Confident of Agreements with Merck and Gilead

Health Minister Humberto Costa said at the end of June that he expects U.S. pharmaceutical companies Merck & Co. Inc. and Gilead Sciences Inc. will agree to reduce prices or allow production of generic equivalents of their anti-AIDS drugs.

Costa said the government is optimistic it will obtain a one-year license to produce anti-AIDS drugs from Merck and Gilead.

"Our expectation is to reach an agreement for voluntary licensing. There have been proposals and counter-proposals. We favor voluntary licensing to make the drugs in Brazil," Costa said.

Vioxx Lawsuits Appearing in Brazilian Courts

Lawsuits involving the anti-inflammatory drug Vioxx of Merck, & Co. are now entering Brazil's judicial system.

Merck recalled the drug in September due to safety concerns of an increased risk of cardiovascular events. The company's Brazilian subsidiary, Merck Sharp & Dohme said that it is aware of some 20 suits filed in Brazilian courts. Over half of them were filed in small claims courts where rulings cannot exceed 40 minimum salaries or R$12,000 (US$5,100).

According to the head of Merck's legal department in Brazil, Eduardo Roncolatto, the company has already won two cases although both have been appealed. Before it was recalled in Brazil, Vioxx's domestic sales were running at US$30 million a year.

Cade May Fine Firms for Vitamin Cartel

The Justice Ministry's anti-trust division, Cade, is studying the possibility of fining three multinational pharmaceutical firms for the formation of a cartel for the sale of vitamins.

The Secretariat of Economic Law (SDE) of the Justice Ministry in June recommended that fines be levied on all three firms—Hoffman LaRoche, Basf and Rhône-Poulenc.

The Brazilian investigation was based on price fixing charges raised against the firms in the United States and Europe. In the US, LaRoche and Basf were ordered to pay fines totaling US$725 million.

In its investigation, SDE concluded that since the policies of the Brazilian subsidiaries of the three companies were largely determined by the parent companies and since the domestic market for the suspected vitamins was dominated by imports, the price fixing abroad contaminated domestic sales of these products.

According to SDE's calculations, Brazil paid an additional US$183.3 million for the imported vitamins while the alleged cartel existed in the 1990s.

In their defense, the three companies stated that there is no evidence that the cartel existed in Brazil or that there was any price fixing on the vitamins in question.

Survey Shows Dissatisfaction with Anvisa

A survey of members conducted by the American Chamber of Commerce for Brazil found widespread dissatisfaction with the operations of the pharmaceutical sector regulatory agency Anvisa.

The principal complaint, endorsed by 80% of the companies interviewed, was that there is little uniformity in Anvisa's decisions which vary widely on the same issues. Health product manufacturers accounted for 34% of the survey's universe and not surprisingly were the most dissatisfied with Anvisa.

Another area of concern was the time period taken by Anvisa to issue rulings on product registration. According to 33% of the respondents, the agency takes between seven and eight months for its rulings and 31% said it takes more than nine months.

Anvisa president Cláudio Maierovitch admitted the "analysis time for registrations is still excessive. But in some cases, as with new medications, the time period should not be reduced because detailed analyses are required."

The survey also found concerns with Anvisa staff, especially agency officials responsible for clearing imports who take an average of 48 hours to clear an imported product compared with no more than four hours in developed countries.

"There are inefficiencies in staff numbers, training and interaction between Anvisa and state and municipal agencies," said Gustavo de Freitas Morais, one of the persons responsible for the Amcham survey.

Movement in Nutritional Supplement's Market

Mead Johnson Nutritionals is considering using

Brazil as an export base to market its nutritional supplement Sustagen in other South American countries.

The plan may also include the manufacture of powdered milk for infants in Brazil and the transfer of Mead's vitamins manufacturing plant in Argentina to Brazil.

At present, Mead, controlled by Bristol-Myers Squibb, manufactures Sustagen and vitamins in Brazil for domestic consumption. Out of the company's US$30 million a year in domestic sales, 70% is the result of sales of Sustagen, 25% from vitamins and the remainder from the sale of the company's infants milk brand Enfamil which is imported.

Mead's Sustagen plant is operating at 55% of capacity and the idea would be to use this excess capacity to produce Sustagen for export throughout the region. Mead is also interested in reducing Nestlé's domination of the US$80 million a year domestic infants milk market. Nestlé's Nan mark has 97% of this market.

In the first step in its planned expansion of Sustagen's South American marketplace, Mead placed its Brazil manager Fernando Mazzarolo in charge of Brazil, Argentina, Uruguay and Paraguay and is planning on investments of US$6,2 million this year and US$8 million in 2006.

Novartis is moving in the same direction with its nutritional supplement Sustacal. The company is turning Brazil into its Latin American base for the product and hired Timothy Altaffer, formerly Bacardi Martini Brazil, to run the division. Next year Novartis plans on launching a promotional campaign centered on supermarket sales.

Sustacal was originally a Mead Johnson product but last year Novartis bought Mead's line of adult supplements worldwide including Sustacal.

The two firms, however, are focusing on different market segments. Mead is pushing its Sustagen Kids brand aimed at children from one to five while Novartis' Sustacal is primarily an adult product also recommended for children over the age of four.

Wyeth Investing in Promoting Vitamins

Wyeth's healthcare division has launched a major promotional campaign in Brazil for vitamins. The company's multivitamin Centrum, is the market leader.

The media blitz is concentrated on television ads and will run until the end of the year.

"We want to increase the public's knowledge about vitamins," said Carlos Sampaio, head of consumer healthcare for Wyeth.

According to Wyeth, only 8% of Brazil's middle and upper classes consume vitamins compared with 40% in the United States. The market for the 12 months ending in April was R$246 million (US$103 million), according to IMS Health.

Centrum led with a 23% market share pursued by its main rivals, Bayer's Supradyn and Pharmaton of Boehringer Ingelheim. Wyeth is hoping that through its promotional campaign, it will increase the sales of the Healthcare Division by 9% this year over 2004's total of R$112 million (US$47 million).

Bristol Picks Brazil for Technical Support Center

Bristol-Myers Squibb announced in June that it has chosen Brazil to be the site of its global technical support center.

Brazil won out over India and Bristol said it will invest US$28 million to set up operations at two sites. In the São Paulo suburb of Alphaville, Bristol will install a center to provide technical support for the firm's employees throughout the world. In Curitiba, capital of the southern state of Paraná, Bristol will open a data center to handle the company's payroll in the United States where it has 20,000 employees.

Juan Manuel Silva Salazar, director of information technology for Bristol, said Brazil was chosen because the company was confident its business information would be well protected here.

"This is an important factor because we are putting in Brazil the data base of our business information," said Salazar. "We believe the Brazilian market has the necessary protection to guarantee that this information will not leave here."

Generics Market Dominated by Four Firms

Five years after the introduction of generic drugs to the Brazilian market, the sector is dominated by four companies which together account for 70% of generic sales.

The market leader is Medley with 2004 sales of R$34.3 million (US$14.4 million) followed by EMS-Sigma Pharma, R$31.7 million (US$13.3 million), Biosintética, R$15.4 million (US$6.5 million), and Eurofarma, R$12.1 million (US$5.1 million), according to IMS Health.

Of these the fastest rising at the moment is EMS which currently has 250 generics on the market and is launching an average of five new ones each month. Its success with generics helped raise EMS' sales in 2004 by 21.5% to R$598 million (US$252 million) and its net profit by 115% to R$49 million (US$20.6 million).

EMS has now embarked on an ambitious project to enter the US market with up to seven medications including generics. The company is expecting a team from the Federal Drug Administration to inspect its factory in the Campinas area of São Paulo state.

The company is already exporting to other developing nations and recently reached agreements with health authorities in Portugal and Hungary.

ECONOMIC AND POLITICAL DEVELOPMENTS

Political Crisis

The government in June found itself facing its most serious political crisis to date following accusations that the PT Party of President Lula had bribed congressmen to vote for government projects.

The scandal came less than a month after accusations that a political party allied with the government had set up a bribery network in the postal service. The government had at first attempted to prevent a congressional investigation of the postal service scandal but with the eruption of a second scandal, government leaders had no choice but to accept the creation of a special investigative committee in Congress.

The congressional bribery charges were raised by Congressman Roberto Jefferson, the controversial president of the PTB Party, a member of the government's congressional alliance.

Jefferson charged that the PT Party made monthly payments of US$12,396 to congressmen from the PP and PL parties in return for their support in Congress. Jefferson, who is one of the persons accused of involvement in the postal authority scandal, also claimed that he had informed Lula of the payoffs.

The two corruption scandals forced the resignation of cabinet head José Dirceu.

In testimony before the lower house ethics council, Jefferson claimed that Dirceu was part of the congressional payoff scheme.

In his congressional testimony, Jefferson spared Lula, stating that the president was not aware of the bribes.

Also the ex-secretary of an advertising executive with close ties to the PT Party told the Federal Police that her former boss handed out the alleged PT payoffs to congressmen.

Press reports stated that the Federal Police had received information from the Central Bank that between July 2003 and this May, two advertising firms owned by the executive withdrew a total of US$8.8 million from their bank accounts. The Federal Police are investigating these withdrawals as well as five contracts the two firms have with the federal government.

Government

President Lula named Mines and Energy Minister Dilma Rousseff to replace José Dirceu as cabinet head.

As minister of mines and energy Rousseff introduced and championed the government's new electricity sector model which has been severely criticized by power companies who claim the model has increased government control over the sector and restricted the ability of these companies to earn enough to cover their investments.

Presidential aides said that Lula selected Rousseff because he wanted a strong manager to take control of the government's inner workings.

Interest Rates

After a nine-month succession of Selic rate increases, the Central Bank in June finally ended its monetary tightening.

With both inflation and inflation projections in decline, the bank's monetary policy committee (Copom) decided unanimously to hold the Selic at 19.75% a year. Brazil's real rate, however, remains the world's highest at 13.9%.

Also, in the minutes of June's meeting, Copom indicated it will maintain the Selic at 19.75% for several months. The financial market, though, is betting that the rate will begin to fall in September.

Business

Industrial production stagnated in April, remaining at the level of March, according to the Brazilian Institute of Geography and Statistics (IBGE).

Versus April of last year, however, industrial output expanded 6.3% and for the year through April rose 4.5% versus the same period last year.

Reflecting a slowdown in investments, output of capital goods declined 2.9% in April from March. Production of intermediate goods rose 1.3%, durable goods fell 0.3% as did the production of semi- and non-durable goods.

Industrial sales in April rose only 0.13% from March although they expanded 2.92% versus April 2004. This left sales for the year up 2.84% compared with the same period in 2004.

Average capacity utilization in April was 82.1%, little changed from 82.3% in March.

Industrial activity in São Paulo slowed in May, according to results released by the state's industrial federation, Fiesp.

Fiesp's Industrial Activity Index (INA) expanded only 0.1% from April, a month that registered a 2.2%

increase versus March.

Compared with May 2004, the INA expanded 4.45% and for the year through May was up 4.7% versus the same period last year.

In another sign of an economic slowdown, nationwide retail sales volume in April fell 0.23% from March.

Compared with April of last year, however, sales rose 3.4% and for the year through April were up 5% versus the same period in 2004.

Trade

Brazil in June posted a trade surplus of US$4.03 billion, the largest monthly surplus on record. This raised the year's surplus to US$19.67 billion, 31.1% above the surplus for the first semester of 2004.

Exports in June totaled US$10.207 billion, another all-time record, versus imports of US$6.17 billion. In the semester, exports rose 23.9% over the same period last year to US$53.6 billion while imports increased 20.3% to US$34 billion. June's exports fell 0.8% on a daily average from May but were up 4.4% year-on-year. Imports declined 7.4% from May but rose 6.6% versus June 2004.

The Financial Market

The dollar in June fell 2.22% to end the month at R$2.334, its lowest level since April 19, 2002.

Investors are bringing money into Brazil and local companies are borrowing abroad to buy government securities, which pay as much as 16 percentage points more than comparable U.S. debt. Through May 31, foreign issues by Brazilian firms had increased 23.5% over the same period last year, totaling US$6 billion.

The Bovespa index of the São Paulo Stock Exchange ended June down 0.6%, increasing its decline for the year to 4.3%.

On foreign markets, Brazil's Global 40 bond reached a record high of 120.25% on June 30 and the country's risk premium in June fell five points to 414 basis points.

Inflation

Wholesale prices continued to fall in June, the main factor behind the month's deflation of 0.44% as measured by the Market General Price Index (IGP-M). June was the second straight month to register deflation and the month's decline was double the minus 0.22% rate of May.

The Broad Consumer Price Index (IPCA), used by the government to track compliance with its inflation targets, fell sharply in May, declining from 0.87% in April to 0.49%.

The May rate was the lowest for the index since October. For the year through May, the IPCA registered inflation of 3.18% and the annualized rate was 8.05%, practically unchanged from April when it was 8.07%.

The National Monetary Council voted to set Brazil's inflation target for 2007 at 4.5%, the same level as the 2006 target.

For this year the target for the Broad Consumer Price Index (IPCA) is 5.1%. While the final rate is expected to be around 6%, the target has a two-point margin of error. This same margin was maintained for 2006 and 2007.

Public Accounts

The consolidated public sector recorded a primary surplus of R$6.3 billion (US$2.6 billion) in May, the highest surplus for May in the Central Bank's statistical series which began in 1991. The surplus was 8.1% over the surplus for May 2004.

The public debt rose nominally by R$957 million (US$403 million) but in terms of GDP fell from 50.4% in April to 50.3%.

With May's results, the total primary surplus for the year rose to R$50.3 billion (US$21.2 billion), also the highest on record and well above last year's surplus of R$38.2 billion (US$16.1 billion) for the same period. The annualized surplus in May was equal to 5.02% of GDP, still ahead of this year's target of a surplus of 4.25% of GDP.

Labor

After remaining at 10.8% for two months, the unemployment rate in Brazil's six largest metropolitan areas fell to 10.2% in May, according to the government's statistics bureau, IBGE.

The work force rose 1.2% from April and 3.8% compared with May 2004, totaling 19.8 million persons. The formal work force expanded 1.8% from April and 7.1% year-on-year, the largest such increase in the history of the IBGE survey.

But while the job picture is improving, salaries lost ground again in May. The average salary fell 1.5% from May, the second consecutive monthly decline. Versus May 2004, the average wage was unchanged.

Foreign Accounts

Brazil posted a current account surplus of US$615 million in May. The annualized surplus declined from 2.2% of GDP in April to 2.06%. Although the trade surplus continued to improve in May, totaling US$3.45 billion versus US$3.1 billion in May 2004, the services deficit rose, increasing from US$1.9 billion to US$3.1 billion. The firming of the real again led companies to alter their timetables for profit remittances. The month's remittances totaled US$1.45 billion, an increase of US$607 million compared with May of last year.

Foreign direct investment slowed in May, falling from US$3.03 billion in April to US$711 million. Although this was in excess of the May 2004 FDI total of US$207 million, it was still the lowest monthly result since last September.

For the year through May, FDI stood at US$7.238 billion compared with US$3.307 billion for the same period in 2004.

Taxes

The government in June unveiled a promised package of tax incentives for the private sector.

The package contains 20 measures including incentives for exports and new investments.

One of the most important measures was the immediate suspension of the industrial products tax (IPI) on capital goods. This was only scheduled to take effect in December 2006.

The package also provides tax exemptions for companies making new investments. To qualify for the tax breaks, companies must show that at least 80 percent of their revenues come from exports.

In a measure designed to spur increased investments in new technologies, companies will be able to deduct 160 percent of their expenditures in research and development. The total will increase to 180 percent in cases when employee expenditures are included and 200 percent if the investments lead to patents.

The Courts

Brazil's new bankruptcy law went into effect in June amid hopes that it will help lower interest rates and increase the volume of bank loans.

The law attempts to streamline bankruptcy proceedings and eliminate the abuses of the previous legislation, approved in 1943, which permitted companies to drag out proceedings for several years.

The main innovation of the new law is the establishment of the concept of "judicial recovery." This will permit companies facing severe financial difficulties to put together a debt restructuring program with their creditors.

A study conducted by Deloitte Touche Tohmatsu estimated that because of the law, bank loans could expand by as much as 26% over the next six years, injecting R$204 billion (US$82 billion) into the economy. This estimate was based on the effects of a similar law in Spain.

Pharmaceutical Market Sales (in US$1,000)

Months	2000	2001	2002	2003	2004	2005
Jan	405,532	351,586	404,276	285,229	428,515	515,412
Feb	460,108	380,517	363,012	370,597	438,602	587,958
Mar	562,209	496,018	551,086	356,867	586,505	726,618
Apr	563,855	511,106	505,749	408,764	566,306	672,773
May	621,041	519,031	518,139	491,713	573,661	759,822
Jun	646,045	534,157	466,099	518,456	575,936	844,438
Jul	589,057	469,046	459,103	502,424	564,137	
Aug	588,960	483,528	392,593	513,324	572,990	
Sept	588,822	422,460	384,989	507,571	562,470	
Oct	522,150	492,823	355,282	556,527	604,564	
Nov	567,170	492,107	419,482	542,827	670,836	
Dec	590,730	533,051	380,683	511,267	633,100	
TOTAL	6,705,678	5,685,430	5,200,494	5,565,566	6,777,622	4,107,019