BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Novartis in troubled waters!

March 10, 2017 | Analysis

Novartis faces corruption charges yet again; and this time in Korea. Novartis is one of the top-selling foreign pharmaceutical companies in South Korea



Swiss pharma giant Novartis has been imposed a fine of 200 million won ($174,628) by the South Korean Health Ministry for allegedly paying kickbacks to promote sales of its medicines. The country's Ministry of Food and Drug Safety said in a statement on its website that it had imposed a three-month ban on the sales of three drugs. The fine is in lieu of a ban on 27 further drugs.

Novartis is one of the top-selling foreign pharmaceutical companies in South Korea, which is the tenth-largest market for the company in terms of sales. The 200 million-won fine is equivalent to a three-month ban of 30 drugs including Novartis' top-selling diabetes treatment, Galvus, according to the ministry.

The Korean Ministry of Health and Welfare said in a statement, that the sales ban will be effective from March 17 to June 16.The Ministry added that it is in the process of reviewing its own administrative actions against Novartis Korea, which could take the form of a fine or a lifting of insurance benefits on drugs sold by the company here.

An official from the Health Ministry's Bureau of Health Insurance Policy told The Korea Herald that it is "carefully deciding" between a fine and an insurance benefit termination, as the latter could block local patients from accessing drugs that may be critical to their health.

Employees of the Swiss giant are accused of paying doctors rebates and kickbacks amounting to 2.6 billion won between 2011 and 2016 in return for promoting Novartis' medicines.

In an e-mail reply Eric Althoff, Head-Corporate Communication, Novartis informed BioSpectrum that On February 22, 2016 the Seoul Western District Prosecutor`s Office launched an investigation into alleged misconduct within our local business operations, focused on alleged interactions with health care professionals through a trade media. "On August 8, the Prosecutor announced charges against Novartis Korea, a number of local associates (Total of 6, 2 current and 4 former) and HCPs (Total of 15). The trial on Novartis Korea and indicted current and former associates in Seoul District Court began on September 22nd and is expected to last 6-10 months."

Immediately after being alerted to the issues raised by the Prosecutor in February this year, Novartis launched its own internal investigation. We regret that this review confirmed that certain associates conducted small medical meetings and other scientific related activities through trade journals, in violation of our policies", he added.

In February 2017 the South Korea Ministry of Food and Drug Safety (MFDS) imposed the following sanctions:

- Zometa, Exelon and Trileptal (a total of 12 SKUs) will be subject to 3 months' sales suspensions.

- Sales suspensions will take effect on March 17, 2017.

- All other products will be subject to substitute fines (capped at a total of KRW 200 million), said Eric.

Trouble for Novartis started a year after Seoul prosecutors began a probe into a massive bribery scandal involving the company's executives and employees in February 2016. Following the investigation, South Korean prosecutors indicted without detention six high-level officials at Novartis Korea last August, including former Chief Executive Moon Hak-sun. The unit's executives are charged with circumventing bribery laws by funding academic events organized by publishers of medical journals and offering kickbacks disgused as attendance fees. In total, as many as 34 people were implicated, among them doctors and the heads of five medical journals.

The case, which is still pending in the Seoul Western District Court, had ignited fresh concerns last year over the continued expansion of illegal kickbacks offered by pharmaceutical companies -- referred to as "rebates" -- to doctors.

Novartis Korea has been operating under temporary CEO Mr Klaus Ribbe since April 2016 when its former chief Mr Moon Hak-sun was removed from his post.

This is not the first time that the Swiss giant is slapped with a fine for illegal practices in Korea. The company was ordered to pay 2.3 billion won in 2011 for offering 7.1 billion won of illegal rebates for three years from 2006.

Novartis and its recent bribery tale!

- Earlier this year, Greece had launched a probe following charges of bribery and illegal practices against Novartis. The investigation was ordered after the country's justice minister responded to media reports alleging bribes by Novartis to doctors and public officials.
- Novartis was investigated by US authorities in 2014 in a bribery case in which payments were made to boost sales of certain drugs. The Swiss drugmaker is fighting a widening lawsuit by U.S. prosecutors who allege its sales force ran a decade-long doctor kickback scheme involving sham events that led to overcharging the federal government. The drugmaker has disputed the allegations, which were filed in 2013
- An anonymous whistleblower has accused Swiss drugmaker of paying bribes in Turkey through a consulting firm to secure business advantages worth an estimated $85 million, according to a Feb. 17 email seen by Reuters.
- Novartis said it agreed to pay $25 million to settle a U.S. Securities and Exchange Commission case that claimed the Swiss drugmaker paid bribes to health professionals in China to increase sales from 2009 to 2013.
- Novartis faced temporary sales ban in Japan as a punishment for allegedly manipulating trial data in favour of its Diovan blood pressure drug and for concealing the side effects associated with its Tasigna leukaemia treatment.

Red Flags are being ignored!

Pharmaceutical companies are facing an increasingly harsh spotlight in the current regulatory environment. The biggest scandal of recent times relates to GSK in China. In 2014, GSK was found guilty of bribery and faced a fine of $490 million. The company was charged with bribing doctors and hospitals to promote GSK products.

A report by Transparency International's *Corruption in the Pharmaceutical Sector* found that despite as much as $300m (£207m) of annual global health expenditure being lost to corruption and errors: "Genuine commitment to anti-corruption policies by heads of governments, senior government officials and regulatory agencies is currently absent in many countries."

The report claimed that World governments and Big Pharma companies are "turning a blind eye" to bribery and corruption that allows a few to make vast profits while damaging the health of many of the poorest people.

Stating that the global pharmaceutical sector was “wide open to corruption”, Ms Sophie Peresson, the director of Transparency International’s pharmaceuticals and healthcare program said in a statement, “It is shocking that despite scandal after scandal, policymakers simply are not taking seriously the corrosive effect of corruption.”

It is important that policymakers and the government must apply stringent measures to curb corruption. The report highlighted that the pharmaceutical industry spends an estimated $42bn [a year] on promotional activities that target doctors, which is equal to $61,000 per doctor on average.

A robust system with a good legal framework is needed to nip corruption off the bud. Unfortunately this is a structural problem and an airtight compliance process is necessary to address this. Doctors, governments, policymakers and pharmaceutical giants must come together and join hands to safeguard the health of the people. But this is far from happening and Novartis Korea case is unlikely to be the last in the series of corruption scandals that we see.