



Drug Makers Want Greater Emphasis on IP Protection in India

US-based drug makers lobby group Pharmaceutical Research and Manufacturers of America (PhRMA) has complained that the positive signals given by India in terms of greater intellectual property protection and market access opportunities are yet to translate into real policy actions and practical changes.

In its annual submission to the United States Trade Representative (USTR), PhRMA highlighted unpredictable patent environment, regulatory data protection failures, high tariffs and taxes on medicines, discriminatory and non-transparent market access policies, and unpredictable environment for clinical research as the key challenges before US companies that operate or wish to tap the Indian market.

The lobby group wants India to remain on the Priority Watch List in the 2018 Special 301 Report of USTR until India addresses their concerns. While acknowledging India's new National IPR (intellectual property rights) policy, PhRMA wanted the country to lay greater stress on effective and meaningful IP protection and enforcement mechanisms.

The Special 301 review is an annual exercise of the USTR to address market access and intellectual property barriers that harm US trade interests. Countries with significant IP concerns for US companies are placed on the Priority Watch List. (Source: Business Today)

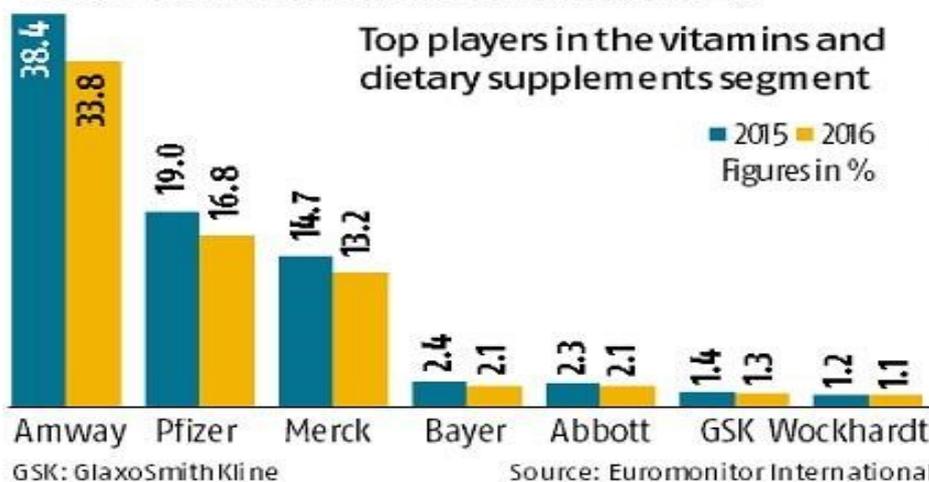
Multinational Firms Dominate Indian Vitamins Market

India's share in the global nutraceuticals market is set to rise, but the vitamins and dietary supplements segment is dominated by multinational companies with limited representation from domestic firms. The top five players in this Rs 1.54 billion dollars market are all MNCs.

Data from Euromonitor show that the US-headquartered Amway has maintained its leadership position in the segment in the Indian market for the past five years. Its share, however, has dipped from a 43.2 per cent in 2013 to 33.8 per cent in 2016.

A recent study by ASSOCHAM and RNCOS highlighted that the Indian nutraceuticals market was expected to touch \$8.5 billion by 2022 from \$2.8 billion in 2015. It also said that India's share in the global market was set to rise from 2 per cent in 2015 to 3 per cent by 2022, given the country's increasing urban belt and growing awareness. Of this, the vitamins and minerals market was expected to reach a value of \$2.1 billion by 2022, said the ASSOCHAM-RNCOS study. (Source: Business Standard)

WHO GETS THE BIGGER SHARE?



Segments that are growing fast

July 2017	Value (₹ cr)	Growth (%)
Cardiac	14,076	11.0
Anti-diabetic	10,258	19.3
Dermatology	6,896	12.5
Vaccines	2,133	18.4
Vitamins/minerals/nutrients	9,945	7.6

Source: AIOCD Pharmasotttech AWACS

“Calm mind brings inner strength and self-confidence, so that's very important for good health”
- Dalai Lama

U.S. FDA Accepts New Drug Application for Prucalopride (SHP555) for Chronic Idiopathic Constipation

Cambridge, Shire plc announces that the U.S. FDA has accepted the submission of a New Drug Application (NDA) for prucalopride. Prucalopride is being evaluated as a potential once-daily treatment option for chronic idiopathic constipation (CIC) in adults.

"Acceptance of the NDA reinforces the breadth and depth of Shire's capabilities in gastrointestinal conditions and commitment to providing new treatment options for patients living with hard-to-treat conditions," said Head of Research and Development at Shire. "If approved by the FDA, prucalopride will be the only readily available 5-HT4 agonist in the US for chronic idiopathic constipation in adults. We look forward to working with the FDA as the agency reviews our application."

"Chronic idiopathic constipation is a commonly-occurring condition that affects nearly one in eight people in the United States," said William D. Chey, M.D., Professor of Gastroenterology & Nutrition Sciences, and Director of the GI Nutrition & Behavioral Wellness Program at the University of Michigan Health System, Ann Arbor. "Many patients use over-the-counter and prescription medicines, including laxatives, but continue to have constipation symptoms."

Prucalopride is an investigational compound, and has not been approved for use by the U.S. Food and Drug Administration.

Prucalopride currently is approved and available in the European Union (EU) where it is marketed by Shire as Resolor®, indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief. It is also available in several other countries outside of Europe. (Source: Nasdaq Global Newswire)

UK PM signals intent to remain with EMA

Prime Minister Theresa May has unveiled the government's desire for the UK to remain part of the European Medicines Agency following its departure from the European Union.



In a key speech on Brexit she revealed that the government will "explore with the EU the terms on which the UK could remain part of EU agencies such as those that are critical for the chemicals, medicines and aerospace industries". This, she said, would mean "abiding by the rules of those agencies and making an appropriate financial contribution".

The UK is also committed to "establishing a far-reaching science and innovation pact with the EU", that would facilitate the exchange of ideas and enable the UK to participate in key programmes alongside EU partners, the PM confirmed.

Healthcare and industry leaders welcomed the announcement. "Every month, 45 million packs of medicines move from the UK to the EU – and 37 million come the other way. That is why the Prime Minister's commitment to seek cooperation on medicines regulation would be the best outcome for patients, not just in the UK but across Europe," said Mike Thompson, chief executive of the Association of the British Pharmaceutical Industry. (Source: Pharma Times online)

Pandemic Capable of Wiping out the Population is on its way, says Health Organisation

A DEVASTATING illness which could wipe out large swathes of humanity is on the horizon, according to senior officials at the World Health Organisation (WHO).

One disease which could kill up to 100 million people in a pandemic similar to the Spanish Flu is long overdue, according to the shock announcement.

This is according to Tedros Adhanom, director general at WHO.

Speaking at the World Government Summit in Dubai, Mr Adhanom said the world is not prepared for such a pandemic and he also states that it could pop up in any country.



Mr Adhanom said: "This is not some future nightmare scenario. This is what happened exactly 100 years ago during the Spanish flu epidemic.

"A devastating epidemic could start in any country at any time and kill millions of people because we are still not prepared. The world remains vulnerable.

"The absence of universal health coverage is the greatest threat to global health. The benefits of universal health coverage go far beyond health. Strong health systems are essential to strong economies.

"We do not know where and when the next global pandemic will occur, but we know it will take a terrible toll both on human life and on the economy."

Mr Adhanom made the bold claims just as the US, which is in the midst of a severe flu season that is causing one in 10 deaths in the US, and the Centers for Disease Control and Prevention (CDC) announced it would be cutting their epidemic prevention programs back by 80 percent.

According to the Washington Post, programs for preventing infectious diseases such as Ebola are being diminished in 39 of the 49 countries they were rolled out in.

In the UK, the Universal healthcare system, the NHS, is constantly facing cutbacks which will "ultimately put patient safety at risk", according a recent report from the Continuing Healthcare (CHC). (Source: Express, UK)

Japanese pharma set for transformation in 2018

This year could see a transformation in the Japanese pharma market, according to a new report, with strong growth stemming from increased use of generics, biosimilars and stronger links with the global industry.

Japan was once the second biggest pharma market in the world behind the US, but has now been overtaken by China.

The CPhI report from UBM says demographic pressures on



healthcare costs are driving a political drive for lower cost solutions. Generics are an obvious route, but Japan's highly developed pharma industry could also begin to make biosimilars too.

Takeda, the country's largest pharma, has been in acquisitive mood recently, and its French CEO Christophe Weber is spearheading a more global outlook from Japan's pharma sector. Takeda has bought its stem cell therapy partner TiGenix for \$626m, with the suggestion that further acquisitions could follow.

Biosimilars growth

In the report, 59% of 41 Japanese pharma companies in an online survey predicted biosimilars will be the fastest growing sector. As the Japanese pharma economy is in a state of transition towards greater openness, potential rewards for early international movers were cited as another key factor in the rapid shifts predicted in 2018. Japan has seen sluggish growth in recent years, but international respondents now predict higher growth potential than most European countries in the league – ranking closely behind Germany and the USA.

Respondents from Japanese pharma also believe that the Japanese regulator has made effective strides in tackling the drug approval backlog, while international respondents largely disagree.

In the area of 'overall competitiveness', Japan also scored positively. International respondents rated Japan almost as highly as India and China (third and fourth), both emerging markets that are widely known for mass production of generics, in contrast to Japan's mature market focussed on quality and innovation. The USA and Germany were first and second.

The report also notes that while partnerships with domestic firms is the optimal strategy for new entrants to overcome obstacles like brand loyalty and lack of local knowledge, there is potential for direct entry and even acquisitions in the medium-term. (Source: Pharmaphorum)

Ghana Needs an Industrial Park to Boost Pharmaceutical Sector

The Government of Ghana will soon earmark a zone for the development of an industrial park exclusive for the country's pharmaceutical industries, Vice President Dr Mahamudu Bawumia has announced.

The move, according to him, will lead to a generation of modern pharmaceutical manufacturing facilities which would be in most competitive position to meet all current international Good Manufacturing Practices (GMP) standards including the WHO-Prequalification standards and to produce high quality affordable medicines not only for local consumption, but also for export into the world market.

Dr Bawumia made this known at the maiden edition of the Ghana Pharma Awards held in Accra.

The government, he further hinted is currently looking at the Ghana Pharmaceutical Sector Development Strategy document and that will consider the proposal to set up a National Bio-equivalence Centre in collaboration with the Pharmaceutical Society of Ghana, Pharmaceutical Manufacturers Association and other stakeholders. The Ghana Pharma Awards seek to recognize excellence and provide recognition throughout the entire supply chain in the Pharmaceutical Industry. Again it is to celebrate thinkers and creators and serve as a strong advocate for individuals and companies that are committed to driving the industry forward.

(Source: The Publisher online.com)

Microsoft and Apollo team up for AI-focussed network in cardiology

Tech giant Microsoft and Apollo Hospitals will work to develop and deploy new machine learning models to predict patient risk for heart disease and assist doctors on treatment plans, both the companies said in a statement.

The AI Network for healthcare is part of Microsoft Healthcare NEXt aimed to accelerate healthcare innovation through artificial intelligence and cloud computing. The team is already working on an AI-powered Cardio API (application program interface) platform.

"AI Network for healthcare aims to democratize artificial intelligence by empowering healthcare providers with faster, intuitive and predictable solutions and reducing the disease burden. The systems of intelligence we create can change the lives of patients and the work of medical practitioners enabling accessible healthcare to all. said Dr. Peter Lee, Corporate Vice President, AI & Research, Microsoft.

Apollo said given its large clinical database and significant pool of clinical talent, this partnership will help impact the global burden of cardiac disease.

"This collaboration with Microsoft's path-breaking technologies like Artificial Intelligence and Machine Learning will help better predict, prevent and manage heart disease in the country. While we commence this in India, we will validate the algorithms and work towards creating a global consortium to tackle multiple conditions in cardiovascular disease" said Sangita Reddy, Joint Managing Director, Apollo Hospitals.

Apollo said over last two years it has been working with a dynamic partner ecosystem of local, regional and global organisations to bring the power of AI to Healthcare. It had first started this with eye care.

(Source: Economic Times)

Health Outcomes Index: Nudging India to Progress

India is committed to the U N’s Sustainable Development Goal (UN-SDG) to ensure “good health and well-being” of all its citizens. The release of “the Healthy States, Progressive India” report has spurred a vibrant debate on the status and future of India’s health sector. This index will help nudge states towards improving their health sector outcomes in the spirit of cooperative and competitive federalism.

India’s southern state of Kerala is the leader among large states, closely followed by Punjab and Tamil Nadu. Uttar Pradesh, Rajasthan and Bihar are the least-performing states. The goal of the index is not just to rank the states based on their historical performance, but also on their incremental performance.

The “Performance on Health Outcomes” index is made up of 24 indicators in three different domains—health outcomes, governance and information, and key inputs and processes. The “health outcomes” account for 70% of the weight, and the other two domains weigh 12% and 18%, respectively.

Key results that emerge from the health index: First, there are large gaps between states. The gap between the best-performing states and the least-performing states is worrisome—Kerala and Uttar Pradesh are separated by 42.86 points, Mizoram and Nagaland by 36.32, and Lakshadweep, and Dadra and Nagar Haveli by 31.15. Two-thirds of our citizens live in states with an overall score less than 60.

Second, incremental performance reveals that there has been a decline in performance on some states: While most states have registered an increase in their health index in 2015-16 relative to 2014-15, six states’ scores have declined—Kerala, Haryana, Gujarat, Karnataka, Himachal Pradesh, and Uttarakhand. These states need to work on health index’s parameters for continuous improvement.

Third, India has made significant strides in achieving the goals set out under the UN-SDG and our own National Health Policy. Some of our states have already met or exceeded the goals a decade ahead of 2030.

National Institution for Transforming India (NITI) Aayog is creating a framework to track the performance of government hospitals based on outcome metrics. Together with the upgrading and setting up of health and wellness centres under the Ayushman Bharat Scheme and the National Health Protection Scheme, these measures will help us realize the goal of “good health and well-being” for all citizens. (Source: mint)

Reva Sudoku

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OxyContin-Maker to Stop Promoting Opioid Painkiller to Doctors

The maker of the painkiller OxyContin is to stop promoting the drug to doctors and halve its salesforce, as it faces a growing number of lawsuits over its role in the US opioid crisis.

OxyContin is Purdue’s biggest-selling drug and is estimated to have generated \$1.8bn of sales last year, down from \$2.8bn five years earlier. The Connecticut-based company is owned by the Sackler family, whose wealth exceeds \$13bn. Purdue said: “We have restructured and significantly reduced our commercial operation and will no longer be promoting opioids to prescribers.”

Opioid overdoses have become the leading cause of death among the under-50s in the US. Opioids, including methadone and fentanyl, heroin and other opiates, were responsible for about 53,000 US deaths in 2016; an average of 146 a day, according to the US Centers for Disease Control and Prevention.

The crisis, which Donald Trump declared a “public health emergency” last year – dates back to the 1990s when healthcare organisations encouraged doctors to treat postoperative pain more aggressively. Soon afterwards drug companies, led by Purdue, started marketing opioids for all kinds of chronic pain, enticing doctors with incentives and all-expenses-paid trips. (Source: The Guardian)

Reva Pharma Participation: 2nd India-Korea Business Summit

New Delhi: Indian Prime Minister Narendra Modi addressed the 2nd India-Korea Business summit jointly organised by The Chosunilbo, Kotra, Invest India, and CII where Reva Pharma was one of the key participants from Indian Industry. Addressing business leaders at the summit the PM said the government was on a drive to improve the investment climate in the country and to create a globally competitive industry through deregulation and minimal state role while enhancing the ease of living of people. Prime Minister also said India is now a “free destination for the enterprise” and “a free and growing market that cannot be found anywhere else”. Assuring Korean business leaders, the Prime Minister said the government is continuously working towards improving the business climate.

Key Participants from The Republic of Korea were:

Mr. PAIK Un Gyu, Honorable Minister of Trade, Industry and Energy, Republic of Korea, Mr.BANG Sang-Hoon, President & CEO, The CHOSUNILBO, Mr PARK Yongmaan, Chairman, The Korea Chamber of Commerce & Industry and Mr. SONG Young-gil, President India-Korea Friendship Association, The National Assembly of the Republic of Korea.

Dr Gurpreet Sandhu, CEO & Managing Director of Reva Pharma had meetings with officials & industry representatives from South Korea.

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