

Additional updates:

1. [Patents, Leather or Fake?](#) – Hindustan Times
Article by Chirantan Chatterjee highlighting steps needed for a robust IP environment. India will have to decide whether it wants to get serious about R&D by taking IPR seriously. He writes, creating IPR is important as more local value-add would mitigate outflow of forex, which is rising exponentially due to import of electronic equipment and services

1. [Patents, Leather or Fake?](#) – Hindustan Times
2. [India must build intellectual property](#) – Economic Times
3. [‘Indian MOM’ shows the way for addressing the problems in healthcare](#) – ETHealthWorld.com
4. [RCEP draft moots tough curbs on cheap medicines](#) – The Hindu
5. [Roadmap to tackle AMR on the anvil](#) – The Hindu
6. [Annus Horribilis](#) – Business Today

2. [India must build intellectual property](#) – Economic Times
The article reflects on India’s reason to build a robust IP model. India is WTO compliant on the subject. And its patent law’s Section 3(d), requiring a novel form of a patent-protected molecule to show improved therapeutic efficacy for it to secure a separate patent, is a model for the rest of the world, even if multinational pharma hates it. The problem in pharma is confined to a trigger-happy attitude towards compulsory licensing that eschews room for negotiated price reductions backed up with bulk purchase commitments orchestrated by the government. For Make in India to be something more substantive than simple assembly of complex parts produced elsewhere, India has to focus on domestic R&D and creation of intellectual property.
3. [‘Indian MOM’ shows the way for addressing the problems in healthcare](#) – ETHealthWorld.com
Highlights the challenges India faces in managing healthcare issues and adopting newer methods and models. One such model is the ‘Indian MOM Model’ – ‘Indian Mars Orbiter Mission’ or the ‘Mangalyan’ model for healthcare. MOM is a disruptive innovation from India which the world is compelled to look at and learn from its success. MOM was the most cost effective inter space mission ever taken anywhere! We need to replicate the success story of MOM / Mangalayan in healthcare. MOM was cost effective (USD 74 Mn), it was asset light (MOM weighed 1ton with 15 Kg of instruments on board) , fast & timely (achieved in 15 months) and it was outcome driven and effective (we landed in our first attempt). Those are the attributes we need to solve our healthcare problems.
4. [RCEP draft moots tough curbs on cheap medicines](#) – The Hindu
The Regional Comprehensive Economic Partnership (RCEP) agreement reveals that the trade pact in its current form could reduce access to affordable medicines in many developing countries. The chapter is leaked and is on Intellectual Property Rights (IPR) is part of an October 2015 draft of the RCEP agreement. From India’s point of view, the draft proposals will compel governments to commit to newer Trade-Related Aspects of Intellectual Property Rights provisions like TRIPS plus — including the Patent Law Treaty (Geneva, 2000), which involve harmonisation in the examination of patent applications and requirements of patentability. The Least Developed Countries (LDCs) are concerned at the move to withdraw the exemption granted under the TRIPS to implement intellectual property laws until 2033. The next round of talks will take place in Perth, Australia, between April 23 and 29.

5. [Roadmap to tackle AMR on the anvil](#) – The Hindu

India is stepping up its fight against antimicrobial resistance (AMR). For the first time, a standard operating procedure will be rolled out for hospitals to not only map drug-resistant infections acquired during hospital treatment, but also bring down infection rates. The US government had last year given a funding of \$8 million through Centres for Disease Control and Prevention (CDC) for a project, 'Capacity building and strengthening of hospital infection control to detect and prevent antimicrobial resistance in India. This project is being jointly executed by CDC, ICMR and AIIMS. The ICMR has been on the resistance trail since 2014 when it set up six nodal centres in four hospitals to record and report drug resistance.

6. [Annus Horribilis](#) – Business Today

Leading pharmaceutical firms have concluded a challenging year. Things may not change anytime soon. The article highlights key challenges of the pharma industry. USFDA inspections and warnings that have impacted the US business, around 45 percent of total sales of most big players. Currency volatility in emerging markets. Step-up in regulatory action in India covering trade margins, marketing code, retrospective pricing and approval to prices of new drugs

1. ['Patent your innovations, claim authority'](#) – Times of India
Intellectual Property Appellate Board (IPAB) organized an event in association with IPR Attorneys Association (IPRAA) to equip students in the field of research and scientific inquiry. At the event, Justice K N Basha, Chairman of IPAB said “Be authority of your own innovations by claiming patents for them”. He cited the example of eminent women personalities like Dr Santha, whose efforts got patent rights for cancer drugs being manufactured in India.

2. [Govt mulling setting up CGMP facility for yellow fever drugs](#) – Business Standard
Government exploring possibility of establishing WHO- approved Current Good Manufacturing

Practice (CGMP) facility for yellow fever drugs. J P Nadda announced that the Zonal Office (Kasauli, Himachal Pradesh) of Central Drugs Standard Control Organization (CDSCO) would start functioning within a week. To ensure production of quality medicines, Nadda also announced three to four comprehensive workshops to be organized in Baddi in May on ‘Good Manufacturing Practices and Good Laboratory Practices’. The Health Minister also launched the website of CRI on the occasion.

3. [Cough cocktail alarm for kids – Drug Companies appeal to court to allow sale of banned syrup](#) – The Telegraph

Several drug companies have approached the court to challenge the Union Health Ministry over the March 10 order for banning sale of cough syrup which contains codeine phosphate, a cough suppressant. The story highlights concerns raised by Drugs Controller General of India (DCGI) over the cocktail formulations. It reports on medical experts questioning the ethics of drug companies seeking to regain the rights.

Quote from Pfizer: Pfizer has claimed its formulation "has a well-established efficacy and safety profile" in India and the formulation has both central and state licences and approvals. Our product is approved for prescription to adults and children depending on their clinical condition, only at the discretion of the treating physicians," a company spokesperson said.

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3. [Cough cocktail alarm for kids – Drug Companies appeal to court to allow sale of banned syrup](#) – The Telegraph
4. ['Secretive' patent talks has generic drug activists worried](#) - DNA
5. ['Indian pharma market growing at over Rs. 2 lakh crore'](#) – Business Standard
6. [Two new cancer drugs to make their way into India](#) – India Today (Mail Today)
7. [Tailor-made TB treatment in offing](#) - DNA
8. [WHO alleges fraud in Semler's Clinical Practices](#) – Economic Times
9. [Pharmaceuticals sage in PET packaging: High-level committee](#) – Times of India
10. [Govt to restrict import of second hand radiology products](#) - DNA
11. [Pharma distributors stuck with banned FDC drugs](#) – The Hindu
12. [Validity of Free Sale Certificate for notified devices extended till expiry of mfg licence to boost export](#) - Pharmabiz
13. [Novartis to prepare the sale of its Roche stake: Sonntagszeitung](#): Reuters
14. Interview: Revolution At GSK India – SCRIP, April 23, 2016, Anju Ghangurde

Quote from Abbott: The formulation was expected to be sold only on prescription by a physician. Our bottle label is in line with Indian regulations - and the product's prescribing information, which is made available to doctors, contains indications, dosage, warning, and precautions as well as contraindications," the spokesperson said, implying that the company's medical representatives caution doctors not to prescribe the drug to children and lactating mothers.

Similar story in Hindustan Times: [Why cough syrups available in India might be harmful for kids](#)

4. [‘Secretive’ patent talks has generic drug activists worried](#) - DNA
The South Asian Chapter of Medecins Sans Frontieres (MSF), via its Access Campaign called on the Indian government to keep resisting proposal that would ‘Limit access to affordable medicines for people in Indonesia, Thailand, Myanmar, Cambodia, Laos who depend on Indian generics’. The proposals pushing for longer patent terms and data exclusivity come mainly from South Korea and Japan, and are being seen as a way to bring the tougher rules under Transatlantic Trade and Investment Partnership (TIIP) and the Trans Pacific Partnership to India. This development may concern Indian generics industry, with the country likely to come under further pressure to toughen its patent laws.
5. [‘Indian pharma market growing at over Rs. 2 lakh crore’](#) – Business Standard
A Jaipur based IIMR University, also a collaborating centre with WHO for district and primary healthcare released a report that ranked the pharmaceutical industry as 3rd in volume and 13th in value across the globe. According to the report, the industry is likely to create over 1.3 lakh jobs in 2016 itself. According to 'Makeinindia.com', the Indian market is the world's 6th largest pharma market and will be the 3rd largest market by 2020. The generics market is expected to grow to \$26.1 billion by 2016 from \$11.3 billion in 2011.
6. [Two new cancer drugs to make their way into India](#) – India Today (Mail Today)
Cancer drug for treating Melanoma may hit the Indian market by September 2016. Medical experts believe the drug approved by USFDA will increase the curability rate by 20 per cent and prolong life of the cancer patients. Keytruda, made by pharmaceutical company Merck, was originally approved by the FDA in September 2014 to treat melanoma. Another drug, Opdivo, will also be made available at the same time. Opdivo is also used to treat melanoma. The one major roadblock in the approval of these drugs is the cost. The drug will cost around 4-7 lakhs and the entire cancer treatment through this drug will go above Rs.1 crore.
7. [Tailor-made TB treatment in offing](#) - DNA
Huge step are being taken towards TB management. According to doctors, the 'Universal drug susceptibility testing' for all TB patients in the city will enable quicker treatment for drug-resistant TB and also control spread of new infections. The Union government has decided that all new TB patients will have their drug sensitive tests, for all 13 available medicines, done before commencing of their treatment. The Centre has also lined up a nationwide TB survey to get a real picture of TB prevalence in the country. The National TB Institute under the guidance of Central TB Division is also kick-starting a pan India survey for prevalence of TB which the results are expected by the end of 2016.
8. [WHO alleges fraud in Semler’s Clinical Practices](#) – Economic Times
Bangaluru based firm was pulled up by the US FDA for data integrity issues. WHO says several staff members on various levels in the organization have to be collaborating and coordinating to execute this type of manipulation. The issue is not confined to a single person operating outside of the quality management system. ‘Manipulation of at least five studies over an extended period of time indicates this is a common practice’, says WHO.
9. [Pharmaceuticals sage in PET packaging: High-level committee](#) – Times of India
A high level committee was constituted by the health and family welfare ministry to assess the health and environment impact of PET usage, after an NGO filed petition against the usage of PET claiming it leaches harmful chemicals. The report submitted by the committee said, ‘Polyethylene Terephthalate (PET) usage in pharmaceutical packaging does not pose a threat to

human health and can be practiced with assurance of safety.' Pharmaceuticals along with soft drinks constitute about one fourth of India's PET packaging industry which is valued at Rs. 4,000 crore

10. [Govt to restrict import of second hand radiology products](#) - DNA

An inter-ministerial committee, headed by Secretary Department of Pharmaceuticals has been set up to restrict imports of second hand radiology products into the country. According to an official notification, 'The committee has been formed to look into the issue of stopping of second hand imports of radiology products into India, including the approval requirements, patients, safety and barriers to domestic industry.' Other members of the committee include a representative of Secretary Department of Commerce, WHO Centre for Health Technology Director and representative of Atomic Energy Regulatory Board (AERB)

11. [Pharma distributors stuck with banned FDC drugs](#) – The Hindu

Pharmaceutical distributors and few medical shops are in a quandary after the Centre's recent ban on Fixed-Dose Combination drugs. Drug manufacturers, who were supposed to take back the FDC stock, are not doing so citing stay orders which they have got from courts in other States, and the medicines which cannot be sold are lying in storage. Even though manufacturers have gotten stay orders, the State government also issued a circular to ban the sale of FDC in Telengana. Till someone challenges the State notification, the ban will be in effect

12. [Validity of Free Sale Certificate for notified devices extended till expiry of mfg licence to boost export](#) - Pharmabiz

The DCGI has issued a directive to all the state drug controllers the extended validity of Free Sale Certificate for notified medical devices till the expiry of manufacturing licence. At present, only 15 medical devices are notified and regulated for its import, manufacture and marketing in the country under the D&C Act & Rules. A Free Sale Certificate with the validity of two years is issued to the manufacturers by the concerned State Licensing Authority (SLA) for export purpose.

13. [Novartis to prepare the sale of its Roche stake: Sonntagszeitung](#): Reuters

As per reports in a Swiss paper, Drugmaker Novartis aims to dispose of a 13.5 billion Swiss franc (\$13.8 billion) stake in its local rival Roche and has already hired banks to support the selling process. The world's biggest prescription drugmaker started building up the stake - worth 33 percent of Roche's voting shares - as a basis for a possible merger more than a decade ago, but the plan never materialized.

14. **Interview: Revolution At GSK India** - SCRIP April 23, 2016, Anju Ghangurde

Brace for GSK India's new avatar. The British multinational is revamping its business model in India and donning a new approach to create, deliver and capture value via a "one team" effort as it strives to emerge as the fastest growing pharma multinational in the country by 2020.

Cross functional "excellence teams", a multichannel approach to reduce "information asymmetry" for customers, calibrating prices to improve access and penetrating deeper into middle and rural India are some of the core components of the ongoing effort.

"Given the new environment in India, we need to re-engineer the business model in a way that we are able to maintain margins but at the same time deliver value of relevance to our stakeholders – physicians, hospitals and the government. The value creation that we are looking at has to be different from what we've done in the past," Annaswamy Vaidheesh, GlaxoSmithKline Pharmaceuticals' vice president South Asia and managing director India, told *Scip* in an exclusive interaction.

Market equilibrium in India has, over the past few years, been significantly impacted by an "aggressive ecosystem" by way of India's national list of essential medicines (typically subject to price caps), escalating expectations on quality standards and regulatory changes. GSK India, once the top ranked company in India, is currently at sixth position as per IMS March 2016 MAT (moving annual total) data.

The GSK India boss touched upon a string of initiatives underway at the company including using digital technology to reach out to customers and taking the concept of "trust in science" to its stakeholders.

The days of medical reps alone delivering messages through visual aids and standard information are passé and GSK India is now building on the use of multichannel approaches, webinars etc. to reach more physicians.

"We want to reduce the so-called information asymmetry by using this multichannel. With this, the ability to create value for customers goes up significantly," Vaidheesh added.

Scrip had previously reported how GSK India had rolled out a [digital initiative](#) in the CNS segment, with an expert digital meeting in the area of bipolar disorder in the Indian perspective.

On building on the "trust in science" concept, the GSK India boss expects to help stakeholders understand "what it takes to do clinical work, write reports, look at data integrity".

"We are looking at medical education from a holistic perspective using digital technology; it could be one way to add value in the new world."

GSK is also beefing up its internal medical capabilities – recruiting doctors "who have what it takes" to share their expertise by reaching out to the ecosystem.

Some of these plans are in sync with GSK's efforts internationally. Globally, GSK at the end of 2013 unveiled three critical changes to reform the way it interacts with HCPs including its intent to stop direct payments to HCPs to speak on its behalf by 2016. It said that instead it expected to develop new digital, personal and real-time applications for better delivery of information to HCPs. It also noted that medical doctors within GSK would have "more time" to talk with their external peers and answer questions about the company's drugs.

GSK is also aligning its public policy with the Indian government's initiatives in the area of public health, adding value to the ecosystem, Vaidheesh said.

"There are multiple ways we are looking at to create value by partnering and how we deliver that value."

Cross Functional Teams

GSK India has also put in place eight cross-functional teams working towards facilitating seamless functioning within the organization while also ensuring it stays nimble-footed in a highly competitive market.

Vaidheesh noted how one such cross functional team – Operational Process Excellence – figures how to put in a process where cost efficiencies are leveraged.

"They will use the Six Sigma technique; we have hired some experts to work with this team and to figure out what are the wastages in the existing processes and eliminate such old processes." Similar cross-functional teams have also been set up in the areas of business development and supply chain excellence, among others.

There is also a thrust on quality excellence, beyond that of just product quality – essentially ensuring that people take accountability for raising the standards in every job that they do.

Products And Pricing

The GSK India boss also underscored the company's intent to bring the right kind of products to India, in the backdrop of the country's improving intellectual property (IP) environment.

"In the respiratory area, we couldn't launch [certain products] because of IP reasons but in today's context, we are confident that the Indian government is supportive of bringing new IP assets. We will make some such assets available in the next four to five years," Vaidheesh added.

On pricing flexibility as was seen in the case of Seretide Accuhaler last year, he noted how the company was experimenting with different models aimed at improving access.

Last year GSK India [slashed prices](#) of its Seretide Accuhaler by 46% to INR540 (then \$8.3). Industry experts then told *Scrip* that while Seretide Accuhaler has generally been perceived as the device of choice by a large number of physicians in key metropolitan areas, affordability issues meant that its use was generally limited to those with severe asthma and chronic obstructive pulmonary disorder (COPD).

Vaidheesh indicated that the price cut had made "tremendous difference" and the company was now able to reach a "large proportion" of new patients coming into that category.

"It [the price cut] seems to be working well. We will continue with that approach. We've tried that with Synflorix, our pneumococcal conjugate vaccine. We are trying to evaluate whether by calibrating prices, we can increase access. It appears that we have made huge headway in pneumococcal vaccines and have been able to dramatically grow in that area," he said.

GSK expects to continue the price calibration exercise for key medicines, where it believes access is a challenge.

"We will continue to tweak and calibrate prices borne out of the fundamental objective of access to medicines," he added.