OPPI

Daily News Monitor

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1. **Health ministry gives point-by-point rebuttal to Lancet editor** – Times of India
New policies and ideas are necessary but it is equally important to consolidate work being done to ensure that services actually reach the people they are meant for, the health ministry has said trashing comments by The Lancet's editor-in-chief Richard Horton that the Narendra Modigovernment is ignoring India's health sector. \

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2. **How Bangladesh, Nepal and Vietnam beat India hollow in health indicators** – Mint
The Lancet is apparently unhappy with the Indian government's attitude to public health care. The government has reportedly refuted the allegations, saying that things are improving. But how does our healthcare effort compare with that of other countries?
Data from the World Bank health indicators show that Bangladesh and Nepal, with per capita gross domestic product (GDP) around half of India's, do much better on health indicators. And Vietnam, with a per capita GDP slightly less than India's, outshines India completely. Forget *The Lancet*—it is the masses of India who should be unhappy with the state of our healthcare.

3. **Innovate in India** – Business Standard
Most of the focus in the past has been on providing products and services needed in the West at a lower cost. For instance, the IT-services boom was triggered by cost arbitrage between the East and the West. What is needed now is to shift focus to solving the problems faced by Indians. For instance, most Indians lack adequate health care. If start-ups can use digital technologies to provide affordable good quality medical diagnosis, those solutions will have

applicability not just in India but all over the world, including in rich countries like the US. This is the reverse innovation opportunity that Indian startups should target. By shifting the focus and solving local problems while at the same time keeping in mind reverse innovation possibilities, start-ups can serve as the catalyst to channel the energy in areas that will help take India global.

In particular, there are low hanging fruits in the areas of healthcare and education. If start-ups can create disruptive solutions here, there is a latent market of 3 billion people that can be served with these same solutions. In addition, many so-called advanced countries, are struggling to cope with out of control healthcare costs and an expensive education system that is out of reach for many, and are looking for solutions that will bend the cost performance curve in a disruptive way. On the other hand, start-ups by their very nature are very risky. Amidst all this euphoria, this message of risk may get lost. It is therefore, important to build a strong and robust ecosystem.

4. **The conundrum of poor quality drugs in India** – Financial Express
In several countries, the term 'counterfeit drugs' has come to represent poor quality medicines and is used in common parlance, although there are major differences in definitions. On account of these differences, there is a great difficulty in exchange of information between countries as well as in estimating the global problem of poor quality medicines. To address this concern, in 2009, the WHO came up with a definition that was considered by many to be broad and ambiguous. A broad definition often creates confusion between legitimate generics and dangerous fakes—therefore, it has been suggested time and again that the term 'counterfeit' should not be used in the context of medicines. Responding to the above criticism, during the 63rd World Health Assembly, it was proposed that until a consensus is reached on how poor quality medicines are defined, the acronym—substandard, spurious, falsely-labelled, falsified, counterfeit medical products or SSFFC—be used. This has given rise to yet another challenge for defining poor quality medicine, as anything in SSFFC becomes everything in SSFFC.

5. **Dr. Harsh Vardhan Urges Indian Pharma Industry to Pursue Serious Research to Provide Quality and Cost Effective Medicines to People** – Business Standard
The Union Minister for Science &Technology and Earth Sciences, Dr. Harsh Vardhan has urged the Indian Pharmaceutical Industry to pursue serious scientific research for providing quality and cost effective medicines to people. He was speaking after presenting the Business Excellence Awards at the India Pharma expo in New Delhi last evening. He said Shri Narendra Modi Government wants to put the science to use and had called upon the pharmaceutical manufactures to take up challenging researches. Dr. Harsh Vardhan said in his ministry under the aegis of Department of Scientific and Industrial Research and Department of Biotechnology researches are going on in the pharmaceutical sector to benefit the people.

6. **Pill that went from $13 to $750 now has a $1 rival** – Times of India
In a demonstration of arbitrary pricing of medicines, pyremethamine, used to treat protozoal infections, went from $13 to $750 a pill in the US, an over 5,000% increase, and down to $1 per pill for a new version, all in a span of just over a month. The new $1 pill is being produced by a small San Diego-based company called Imprimis Pharmaceuticals.

Daraprim, or branded pyremethamine, was bought from its producer by Turing Pharmaceuticals owned by a hedge fund manager Martin Shkreli, who then hiked the price to $750 becoming "the poster child for big pharmaceutical greed".

7. **India to push for social security pact again at trade policy forum with US** – Hindu Business Line
An India-US totalisation or social security agreement — that could exempt short-term Indian workers in the US from contributing to social security — will top India's agenda at the bilateral trade policy forum (TPF) meeting to start later this week in Washington.

"While we will also talk about visa issues and better access for our agricultural products, a totalisation agreement is the big-ticket item for us," a Commerce Ministry official told *BusinessLine*.
US Trade Representative (USTR) Michael Froman will meet India's Commerce and Industry Minister Nirmala Sitharaman for the ninth TPF on October 29 where the two will discuss a range of trade and investment issues concerning each country.

Other issues to be taken up include fast-tracking an inspection mechanism for farm goods where facilities would be given prior approval by US officials and individual consignments will not have to be inspected and greater transparency in actions against Indian pharmaceutical companies by the US Food and Drugs Authority.

8. **New drug launches take a hit in India amid tight USFDA scrutiny** – Indian Express
At a time when a number of Indian drugmakers have come under the US Food and Drug Administration (FDA) sanctions due to quality-control issues at their manufacturing plants, Indian pharma firms are also witnessing a slowdown in launching of new drugs as the agency increases scrutiny of generic companies.

"The new drugs are approved as per the guidelines and requirements specified in Rule 122A, 122B, 122D, 122E and Schedule Y of Drugs and Cosmetics Rules, 1945… There has been a slowing down in the number of new drug molecules approved by the CDSCO. The launching of new drugs are done by the manufacturing companies taking into consideration all aspects including their business interest," an official with the Ministry of Chemicals and Fertilizers said.

Data from CDSCO indicates that since the year 2011, when a total of 41 new drug molecules were approved, the number has dwindled down since, with a minor pick-up last year. The CDSCO has cleared 11 new drug molecules till end-June 2015, according to the data. Growth in US sales of Indian drugmakers also slowed to 14 per cent in the year to March 2015, which is less than half of what it was in the year to March 2012, according to brokerage Edelweiss.

9. **Drugmakers plan to get together to discuss how to get out of FDA warnings and bans** – Economic Times
Indian drug companies that have been swamped by warnings and bans issued by the US Food and Drug Administration in recent years are planning to get together to exchange notes on how best to get out of such jams as they seek to protect exports to the world's biggest market for pharmaceuticals.

The idea is to address key issues related to quality, manufacturing and process compliance in order to identify solutions, several people aware of the development told ET.

Top executives of the largest Indian generic firms including Dr Reddy's Laboratories, Sun PharmaceuticalBSE -0.44 %, Torrent Pharma, Zydus Cadila and Lupin Pharmaceuticals met informally in Mumbai recently to discuss a common platform and brainstorm on ways of resolving FDA strictures. None of the companies mentioned responded to queries as of press time.

Last year, then US FDA commissioner Margaret Hamburg visited India and signed a deal to cooperate with the country's regulatory agency on sharing knowledge.

She stressed how quality was a recurring theme during her visit. In an official blog post, Hamburg wrote: "In recent years, FDA has identified significant lapses in quality by some companies operating in the US and around the world. As a result, American consumers have had to endure greater risk of illnesses, recalls, warnings about products many of them rely on each day. This is unacceptable. Consumers should be confident that products they are using are

safe and high quality and when companies sacrifice quality, putting consumers at risk, they must be held accountable."

10. **Pharma firms panic as Govt looks to cap trade margins** – Bloomberg TV
    Pharma companies are in a state of panic as the Department of Pharma is considering capping the trade margins on generic drugs.

    Pharma Secretary VK Subbhuraj recently convened a meeting, which was attended by senior officials of pharma companies including Abott, Cipla, Intas Pharmaceuticals and Alkem Laboratories, to express the government's concern over astronomical trade margins and the ardent need to cap margins, sources said. Subbhuraj asked companies to submit their cost sheets to that prove that they are not providing huge margins to the traders for generic sale.

    On August 27, Bloomberg TV India reported that astronomical retail margins of up to 4,000 per cent on generic drugs have come under the scanner of the PMO.

    While dismissing reports that trade margins are as high as 4,000 per cent, pharma companies have expressed their displeasure over the government's move to cap margins at 35 per cent as it would render selling drugs in far flung places unviable.

11. **R&D spending of 25 India pharma cos soar by 28.8% in 2014-15** – Pharmabiz
    Indian pharmaceutical companies have substantially stepped up investments in R&D during 2014-15 to overcome stiff competition and to create product pipeline and strengthen their presence in world market. A Pharmabiz study of leading 25 companies shows that there is a 28.8 per cent growth in R&D expenditure at Rs. 9,250 crore during the year ended March 2015 from Rs. 7,179 crore in the previous year. These companies have spent almost seven per cent of their consolidated net sales in 2014-15, which is slightly higher from 6.6 per cent in the previous year.

    These companies have created strong product pipeline by filing ANDAs, DMFs and patents in the world market. With rising healthcare cost, several countries are undertaking cost cutting measures and moving towards cost effective generics and biosimilars products. Indian companies are focusing on novel drug discovery & development (NDDD), generics, biotechnology and biosimilars. These companies are taking steps to strengthen intellectual property area to tap expiration of patent opportunities.

12. **The strike that wasn't** – The Hindu
    Last week, about 8.5 lakh chemists in India shut down their pharmacies, hoping to nudge the Ministry of Health into acting against online pharmacies. The pharmacists were making a fairly simple argument: as things stand, India did not have a law to regulate online sale of medicines and hence the start-ups need to shut shop.

    However, as it now turned out later, the fountainhead of this nationwide strike was a rumour spread by a group of completely ill-informed chemists, frustrated by the Ministry of Health's silence on the subject. Added to this mix was a court case against e-commerce major Snapdeal.com and a possibility of a midweek holiday for chemists. In May this year, Harshdeep Kamble, commissioner of the Food and Drugs Administration (FDA) Maharashtra, filed a first information report (FIR) against Snapdeal for selling prescription drugs online. The complainant alleged that the online retailer was in violation of the Drugs and Cosmetics (D and C) Act, 1940, and the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

    This is accurate. The D and C Act does not permit online sale of medicine. However, it does not allow home delivery of prescription drugs either.

13. **Strong and Healthy** – Business Today
    Big is getting bigger in the global pharma industry. Israeli giant Teva Pharmaceutical Industries acquired the generics business of leading US player, Allergan, for $40.5 billion in July. Mylan N.V., which is now domiciled in the Netherlands with operational headquarters still out of the US, is pushing for a $33-billion hostile takeover of Ireland-based Perrigo, a maker of over-the-counter cough and allergy remedies. There have been a number of other M&As among US-based pharmacy chains or pharmacy benefit managers - intermediaries between drug companies and insurers - in the last few years. Will such consolidation impact the strength and influence of other players in the long term, especially Indian pharma companies operating in global markets?

14. **FDA increases approval for generic drugs** – Asian Age
    Approvals of ANDAs (Abbreviated New Drug Applications) by the US Food and Drug Administration (FDA) have picked up substantially, with 75 approvals in the April to September 2015 quarter as against 72 in Financial Year 2015 (Apr 2014-Mar 2015).

    Similarly, says an India research report on pharmaceuticals for the October 2014 to September 2015 fiscal, FDA has approved 492 ANDAs, one of the highest approvals in any of the past seven years.
    Faster generic approvals won't require legislative action, the report notes and says that the general perception among the investor community is that action from the US FDA is a lot more likely than a legislative fix and that faster approvals from FDA will hit generic firms' adversely.

    "While we do recognise that quicker approvals from FDA will promote competition among companies and affect prices in general, the actual impact by company would depend on product and pipeline mix."

15. **NITI Aayog panel raps business environment** – Business Standard
    A panel of experts asked by the NITI Aayog to examine the current initiatives on innovation and entrepreneurship in India has found the country's business environment unfriendly and not conducive for corporate investment.

    Complicated tax regime, difficulty in shutting down failing businesses, weak intellectual property regime, unfavourable regulatory frame-work, complex and cumbersome labour laws and infrastructure defict all create barriers to entrepreneurship, the report said.

    Officials said some of the recommendations could form part of the 2015-16 Union Budget.

16. **IPRs acquired get tax benefit: SC** – Business Standard
    When a company acquires the plant of another, intellectual property such as brand name, copyright and know-how are of capital nature and it can claim deduction or depreciation in income tax, the Supreme Court has ruled. In this case, Mangalore Ganesh Beedi Works vs CIT, the partnership was dissolved and a new company consisting of association of persons was formed to continue the business. The new entity claimed depreciation under of the Income Tax Act towards acquisition of IPR. In the alternative, it claimed depreciation on capitalising the value of IPR by treating them as 'plant'. The tax authorities rejected the claim. After appeals in forums below and the Karnataka high court, the question was raised by the firm in the Supreme Court: Would intellectual property come within the definition of 'plant'? The court answered yes, "for the reason that there can be no doubt that for the purposes of a large business, control over IPR is absolutely necessary." Further, the judgment explained that "the acquisition of such rights and know-how is acquisition of a capital nature.