

Daily News Monitor

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- Health is wealth: A redesigned national health insurance policy promises to improve India's social safety net Times of India
 - Indian governments have an abysmal record in providing healthcare. Among major economies, India has perhaps the most vulnerable population when it comes to dealing with health emergencies. Around 58% of total healthcare
 - expenditure is borne by patients directly, without insurance or reimbursements.

Since 2008, central governments have tried to address the problem through a cashless national health insurance

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scheme, RSBY, for economically vulnerable people. In a welcome move, health ministry plans improvements here by bundling RSBY with a few other schemes, and enhancing the extent of insurance cover. A well designed health insurance scheme is a key component of a social safety net.

Make in India: Can India be a hub for the \$200 billion worth biosimilars opportunity – The Economic Times

The Indian generics industry got its first big break in 1984, when the US passed what is known as the Hatch-Waxman Act. With this legislation, the US streamlined the generic approvals, thereby making it easier for generic companies to compete in the US drug market. Observers of the pharmaceutical industry consider today's opportunity for India in biosimilars as not being different from that of the generics industry in 1984.

Policy-makers in most countries now feel the need to allow biosimilars. As the biologics are priced very high, it is necessary for countries to reduce prices through biosimilars. In recent times, patents of some biologics have expired and more will expire before 2020. Even the Big Pharma embraced biosimilars, beginning with Merck in 2008. Now, there are about 600 biosimilar products in development around the world, according to market research firm Roots Analysis.

3. Generic drugs: 'India must give written declaration on compulsory licensing' – The Hindu Business Line

Mukesh Aghi, President, US-India Business Council (USIBC), said although India has given verbal assurance on not issuing compulsory licences for generic drugs manufacturing, the American industry is keen on a written declaration. In an interview with BusinessLine, Aghi also said the government should revisit the draft model of the Bilateral Investment Treaty (BIT).

It is true the government has reassured industry verbally in meetings that they will not use compulsory licences. However, verbal assurance could be easily undermined if personnel or government officials change swiftly. Investor sentiment would be more confident if the government provides a written declaration, saying they have officially disbanded the interagency compulsory licence committee and that compulsory licences will not be used except under situations of public health emergencies.

India has dedicated resources to enforcing copyrights and preventing pirated goods from entering the market. USIBC looks forward to working with the Indian government's enforcement authorities to ensure that the inflow of fake and pirated goods is prohibited and enforced. The US and Indian authorities have previously cooperated on raids of markets and other locales of pirated goods and looks forward to collaborating and training for greater enforcement.

4. Opinion: The rationale of India's drug policy – Mint

The Supreme Court's description last year of India's drug pricing policy—irrational and unreasonable—is unfortunately accurate from several angles. There have been two contradictory developments over the past few days: there is now a possibility that stents (a small mesh tube used to treat narrow or weak arteries) will become a component of the National List of Essential Medicines (NLEM). And a fortnight ago, customs duty exemptions on a number of drugs were lifted. Both are instances of the juggling act any government must carry out to achieve the twin objectives—interdependent and yet often pulling in opposite directions—of enabling broad access to reasonably priced medicines and allowing the marketplace to function well enough for pharmaceutical companies to invest in innovation. No administration in New Delhi has quite managed to pull it off yet.

5. Govt restores customs duty exemption on 3 drugs – Business Standard

Within days of withdrawing customs duty exemption on a host of life saving drugs, the government today restored exemption on three of those drugs that are mainly used for treatment of hormonal disorders, growth failure and haemophilia.

The Central Board of Excise and Customs (CBEC) in a notification restored import duty exemption on three drugs -- Octreotide, Somatropin and Anti- Haemophilic Factor Concentrate (VIII and IX).

6. **Bulk drug policy to be unveiled** – The Hindu

Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers is expected to come out with a new bulk drug policy in less than a month with an objective to grow the Indian pharmaceuticals sector to a \$200 billion industry by 2030.

Under this policy, the government wants to build an ecosystem to help pharma companies to move up in the value chain and develop new molecules through innovations.

"We are coming out with a new policy. This policy should been announced six months back. Now it will be unveiled in less than a month," said Dr V K Subburaj, Secretary, Department of Pharmaceutical, Ministry of Chemicals and Fertilizers said.

7. **Opinion: Why cap prices of medical devices** – The Financial Express

Access to healthcare is one of the parameters on which the success of any welfare state can be measured. India has its own share of healthcare burden, and citizens' access to medicines has attracted attention from successive governments. Whereas the political will to provide adequate healthcare access has been dampened by resource crunch, governments have rather passed the buck on the issue to the industry by exercising price controls over medicines.

While medicines have been under some or the other form of price control, now there has been a widening of interest to cover certain medical devices under price controls as well, especially in case of cardiac stents, orthopaedic implants and intra-ocular lenses. The argument is that these devices are sold in trade channels with too wide a margin and that patients are burdened with exorbitantly high prices.

8. AstraZeneca wins FDA breakthrough status for key cancer drug – The Economic Times
The U.S. Food and Drug Administration has granted breakthrough therapy designation to
AstraZeneca's biggest new drug hope durvalumab as a treatment in bladder cancer, the
drugmaker said on Wednesday.

The experimental medicine is a so-called PD-L1 therapy that fights cancer by boosting the immune system.

Breakthrough therapy designation expedites the development and review of medicines intended to treat serious or life-threatening diseases.

9. Glenmark gets tentative nod from USFDA for azelaic acid gel – ET Health

Glenmark Pharmaceuticals today announced receipt of tentative approval from USFDA for its generic version of azelaic acid topical gel used for treating skin inflammation.

Glenmark will market this product upon receiving final approval, it said, adding that the patent for Finacea topical gel, 15 per cent, is scheduled to expire on November 18, 2018.

10. Budget wishlist: Health care sector – Business Standard

Universal health care for enhanced financial access and physical access to medical care.

- Regulatory framework and incentives for start-ups in the health care sector, especially in Tier-II cities and beyond.
- Development of skilled human resources in health for traditional health care delivery models (hospitals, nursing homes) and newer delivery models (home and digital health care).
- 11. <u>Cabinet approves Agreement for collaborative activities in the area of Traditional Medicine</u> <u>between Ministry of AYUSH and the World Health Organization</u> Business Standard

The Union Cabinet chaired by the Prime Minister Shri Narendra Modi has given its approval to the Agreement for collaborative activities to be signed in the area of Traditional Medicine between Ministry of AYUSH, Government of India and the World Health Organization, Geneva.

The long-term collaboration with WHO would help in improving International acceptability and branding of Ayush systems, facilitate awareness generation regarding AYUSH systems of Medicine by means of education, skill development, workshops, publications and exchange programs between AYUSH and WHO for capacity building, facilitate advocacy and dissemination of information on AYUSH systems amongst the Member States; collaboration with third Parties for creating synergies in implementation of WHO Traditional Medicine Strategy 2014-2023 particularly in the context of AYUSH systems.

The expenditure for carrying out collaborative activities will be met from the allocated budget under the existing plan schemes of Ministry of AYUSH.

12. <u>Health min releases Rs 10 cr to HP for 3 new medical colleges</u> – Business Standard

The BJP today said Union Health Ministry has released Rs 10 crore to Himachal Pradesh for setting up three new medical colleges and improve the health-care infrastructure in the state.

"The grant-in-aid has been released for establishment of new medical colleges by upgradation of district hospitals. It has released Rs 4 crore for district hospital in Chamba and Rs 3 crore each for district hospitals in Hamirpur and Nahan, a BJP release here said.

Quoting Union Health Minister JP Nadda, it said the current grant-in-aid was part of the sustained efforts by the Ministry to improve the health infrastructure in Himachal Pradesh.

13. Health ministry study recommends increase in tax on tobacco – Mint

Consuming tobacco is becoming more affordable in India, shows a study by the Union ministry of health and family welfare. Even though prices of bidis and cigarettes have increased in the last few years, the increase is less compared to essential food items.

The study, titled "Tobacco Taxes in India: An Empirical Analysis", also found that share of taxes in cost of tobacco products declined from 2006-07 to 2012-13.