

1. [Government caps price of 6 formulations packs](#) – The Economic Times

Government has capped prices of six drug formulations packs, including pain killer Ibuprofen, anti-infective Metronidazole, among others.

Drug firms such as Abbott Healthcare, Ipca Laboratories and Merck would be impacted by National Pharmaceutical Pricing Authority's (NPPA) move.

The prices of six formulation packs have been fixed/ revised under Drug Price Control Order (DPCO), 2013, NPPA said in a statement.

2. [Government eases testing norms for new drugs approved overseas](#) – The Economic Times

India has taken a series of steps aimed at easing rules for tests and clinical trials needed before the introduction of drugs that have already been approved in other countries.

The move places greater responsibility on the ethics committee that vets clinical trials and is expected to cut timelines for the launch of new medicines, including biologics. The Central Drug Standard Control Organization (CDSCO) notified the changes through a November 10 circular.

3. [India, EU unlikely to conclude FTA in near future: Assocham](#) - The Economic Times

India and the European Union are unlikely to conclude the free trade agreement negotiations in the "near future" given a complex nature of the the 28-nation bloc and its vast internal issues, Assocham said today.

As negotiations for a Broad-Based Bilateral Trade and Investment Agreement (BTIA) with the European Union (EU) are heading "nowhere", India should press for a separate free trade agreement with Britain, the industry chamber said.

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4. [US court imposes temporary sales ban on Dr Reddy's generic antacid](#) – ETHealthWorld
5. [India is committed to protect Intellectual Property Rights: PM Modi](#) – Business Standard
6. [Personnel shortage, lack of funding hold back India's drug regulator](#) – Business Standard
7. [Novartis, Roche find 'outcome-based' drug pricing an elusive dream](#) – Reuters
8. [U.S. appeals court invalidates four Merck Cubicin patents](#) – Reuters
9. [Pacific trade deal could limit affordable drugs - world health chief](#) – Reuters
10. [Delhi cabinet approves Rs 209 crore to set up 1,000 healthcare clinics](#) – Mint
11. [Pharma regulation: Getting the dose right](#) – The Financial Express
12. [MSF expresses concern over inclusion of dangerous provisions in TPP between US & Pacific Rim nations](#) – Pharmabiz.com

Expressing disappointment and concern over the EU banning sale of around 700 pharma products clinically tested by GVK Biosciences, India has in August deferred the talks with the EU on the proposed free trade agreement.

4. [US court imposes temporary sales ban on Dr Reddy's generic antacid](#) – ETHealthWorld
US court has temporarily stopped Dr Reddy's Laboratories from selling a generic version of AstraZeneca's antacid Nexium in that market over allegations of trademark infringement.

The order of the District Court in Delaware has come on a suit filed by AstraZeneca, which objected to the Indian company using purple colour for the generic version.

AstraZeneca has used the purple colour to market Nexium and Prilosec, which are used for the treatment of severe gastric diseases, besides having the trademark over the name 'The Purple Pill'.

5. [India is committed to protect Intellectual Property Rights: PM Modi](#) – Business Standard

Prime Minister Narendra Modi today assured the business honchos in the UK that India is committed to protect Intellectual Property Rights of all innovators and entrepreneurs and said that a comprehensive National IPR policy is being finalized. "I am personally convinced and want to assure you that India is committed to protect Intellectual Property Rights of all innovators and entrepreneurs. We have taken several initiatives for transparency and online processing in IP administration. A comprehensive National IPR policy is being finalised," he added.

6. [Personnel shortage, lack of funding hold back India's drug regulator](#) – Business Standard

The shortage of personnel and lack of regular training are a threat to the Indian drug regulatory mechanism, which could dent the Indian pharmaceutical sector's international reputation, say experts. Almost half of the positions in the Central and state drug regulators remain vacant, and the existing staff is not trained to meet the regulatory requirements of the growing sector, they add.

The Centre recently approved Rs 1,750 crore to strengthen the drug regulatory system in the country. This Rs 900 crore would be for strengthening the Central Drugs Standard Control Organisation (CDSCO) and Rs 850 crore for state drug authorities.

7. [Novartis, Roche find 'outcome-based' drug pricing an elusive dream](#) – Reuters

News that Novartis's heart drug Entresto cuts the risk of re-hospitalization might have helped Chief Executive Joe Jimenez realize his ambition of getting insurers to pay more for treatments when they cut overall medical costs.

Instead Jimenez and Severin Schwan, CEO of cross-town rival Roche, have been forced to concede that insurance companies, especially in the United States, are not yet ready for such "outcome-based" pricing models. A key hurdle, Jimenez and Schwan said in recent interviews, is that electronic medical record systems aren't capable of accurately tracking a drug's role in reducing hospital stays or preventing further trips to the emergency room.

This gap has largely stymied a push to change how drugs are priced and reimbursed by insurers and governments, even though both CEOs contend today's pay-per-pill approach can't be sustained.

8. [U.S. appeals court invalidates four Merck Cubicin patents](#) – Reuters

Drug maker Merck & Co Inc said the U.S. Court of Appeals for the Federal Circuit invalidated four patents related to the antibiotic, Cubicin, that expire in 2019 and 2020.

The drugmaker had sued Hospira, now a unit of Pfizer Inc , in March 2012, saying Hospira's application to sell a generic version of the antibiotic infringed five patents.

Thursday's decision will keep a Cubicin generic out of the market only until June 2016. The court invalidated four of Merck's patents that would have protected the drug's market share up to 2020.

New Jersey-based Merck said it would review the court's decision and consider steps including seeking a further review by the Federal Circuit or Supreme Court.

9. [Pacific trade deal could limit affordable drugs - world health chief](#) – Reuters

A massive trade pact between 12 Pacific rim countries could limit the availability of affordable medicines, the head of the World Health Organization said on Thursday, joining a heated debate on the impact of the deal.

Margaret Chan told a conference there were "some very serious concerns" about the Trans-Pacific Partnership (TPP), a central plank of U.S. President Barack Obama's trade policy which still needs to be ratified by member governments.

But other bodies, including leaders of India's \$15 billion pharmaceuticals industry, have said it could end up protecting the patents of powerful drugs companies inside the deal area, at the expense of makers of cheaper generic drugs outside.

10. [Delhi cabinet approves Rs209 crore to set up 1,000 healthcare clinics](#) – Mint

The Delhi state cabinet chaired by chief minister Arvind Kejriwal on Tuesday approved the allocation of Rs.209 crore to set up 1,000 Aam Aadmi Mohalla Clinics across the national capital. Mohalla is Hindi for neighbourhood. The state government, in its first budget presented in June, made provision to set up 500 such local clinics to provide quality public health care.

11. [Pharma regulation: Getting the dose right](#) – The Financial Express

A manufacturer's critical role in ensuring supply of good quality pharmaceuticals requires both strong laws as well as their effective implementation via compliance. While addressing the former, the Drug Controller General of India recently announced that it shall put before the government a proposal to upgrade the current manufacturing laws so that they meet stricter international standards. Such an amendment, if eventually brought about, might present some challenges to begin with, but with uniform and effective implementation it promises to pave the way towards greater confidence-building, thereby making India a widely acknowledged source of safe and efficacious drugs.

12. [MSF expresses concern over inclusion of dangerous provisions in TPP between US & Pacific Rim nations](#) – Pharmabiz.com

The international humanitarian organisation the Médecins Sans Frontières (MSF) has expressed concern over the inclusion of dangerous provisions in the Trans-Pacific Partnership (TPP), between the US and 11 Pacific Rim nations, that would dismantle public health safeguards enshrined in international law and restrict access to price-lowering generic medicines for millions of people.

The Trans-Pacific Partnership (TPP) is a trade agreement negotiated between the US and eleven other Pacific Rim nations: Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. After more than five years of negotiations conducted in secret without the opportunity for public review, the agreed text, which will now be submitted to national processes for final signature and ratification, has been officially and publicly released.