

1. [Pharma firms divided on drug trial proposal](#) – Business Standard

A central government move to extend the trial validity period of new drugs from four to 10 years has divided the pharmaceutical industry.

All applications for manufacture of new drugs are required to be made to the central drug licensing authority for four years. And, require the applicant to do clinical trials and bio-equivalence studies. After four years, state licensing authorities can grant approval. The suggestion now is to extend this four-year period to 10 years.

The Organisation of Pharmaceutical Producers in India, representing multinational drug makers has welcomed the proposed amendment. "This would be a step towards ensuring patient safety. We do not think such a provision can in any way be seen as a data exclusivity provision," said Kanchana T K, Director-General, OPPI.

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10. [IMPLEMENTING PPR 2015](#) – Pharmabiz.com

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- [Pharma companies lock horns on move to extend drug validity rules](#) – Business Standard

2. [A due recognition](#) – The Asian Age

Taking inspiration from Marie Curie's life, Hyderabad based Dr Prathama S. Mainkar has dedicated her life to research. She is the Senior Principal Scientist of CSIR-Indian Institute of Chemical Technology and was recently awarded the Woman Scientist Award by the Organisation of Pharmaceutical Producers of India (OPPI). OPPI represents research-based pharmaceutical companies in India and has been appreciating work done in the pharma field since 1965. This recognition is bestowed on her for the remarkable contributions made to the pharmaceutical industry, both in early drug discovery and process development for generics.

3. [Government may disband National Pharmaceutical Pricing Authority](#) – The Economic Times

In a major overhaul of the country's drug policy, the government is likely to soon disband the National Pharmaceutical Pricing Authority (NPPA) in its present form and assume the power to set prices of essential medicines, as it seeks to address concerns that excessive controls were stifling innovation and competitiveness of the sector. The revamped policy will also delink price control

from essential medicines. Under the current regime, the moment a drug is brought under the list of essential medicines; it is subject to the price control mechanism.

4. [\*\*Delhi HC turns 50: Five landmark intellectual property rights rulings – Mint\*\*](#)

The Delhi high court since its inception 50 years ago has emerged as a hub for intellectual property right (IPR) cases. The institution has helped shape intellectual property law by interpreting various facets of the trademark, copyright, patent law and coming up with innovative solutions. Many of its rulings have become path breaking in their own ways and have become a precedent for other courts both at home and abroad.

The court has taken cognizance of all kinds of commercial and company intellectual property (IP) matters through the years and set out important principles under IP law such as that of “trans-border reputation”, “well-known trademarks”.

5. [\*\*Govt considering a "form of data" exclusivity to give protection to Big Pharma – The Times of India\*\*](#)

The government is considering to introduce a form of 'data exclusivity', a provision which will potentially give protection to Big Pharma, thereby delaying generic competition and hence impacting access and affordability of drugs. The department of industrial policy and promotion, an arm of the commerce ministry, is understood to be keen to extend the four-year period (given at the time of drug approval) to 10 years, extending the protection (exclusivity) to the drug.

Experts of industry say such a move would compromise competition, access and affordability of medicines, with its impact being even worse than regulatory data protection. Such a rule would apply not only to patented medicines, but even to the off-patent medicines introduced for the first time and even to medicines whose patents are invalidated.

6. [\*\*Health ministry's plan to focus on lung disorder – The Times of India\*\*](#)

The Union health ministry will soon release, what is being called the "New Delhi declaration on mitigating effects of air pollution". This will offer a time-bound action plan to different ministries to address various sources of air pollution. The health ministry has also decided to include chronic obstructive pulmonary disorder (COPD)—a health condition closely associated with exposure to toxic air—in the non-communicable diseases (NCD) programme.

It has recently held a meeting with the steering committee constituted to look into air pollution. The panel released a report in August last year and had been discussing the need to include COPD in NCD programme since then but the ministry finally took the decision to include it only last month. "All states have been asked to include COPD in the NCD programme. The issue will also be discussed with all BRICS nations during our meetings on November 17 and 18 because all these nations are affected by this problem," said Dr Damodar Bachani, deputy commissioner (non-communicable diseases) at the health ministry.

7. [\*\*India, China have the largest number of breast and cervical cancer patients – Hindustan Times\*\*](#)

According to a recent study published in the Lancet, India and China have the largest number of women with breast and cervical cancer. Cervical and breast cancer kills 8,00,000 women around the world every year — with two-thirds of breast cancer deaths and nine out of 10 cervical cancer deaths occurring in low- and middle-income countries. Five-year survival after diagnosis for breast cancer ranges from around 50% in South Africa, Mongolia and India, to over 80% in 34 countries, including Australia, the UK, Ireland, France, Germany and the US, highlighting huge inequalities in access to prevention, early detection, and treatment.

8. [\*\*Reports warn of explosion in cancer deaths among women – Mint\*\*](#)

Two reports have warned of an explosion in cancer deaths among women, with a toll, mainly from breast cancer, of some 5.5 million per year by 2030—roughly the population of Denmark. This

represented a near 60% increase in less than two decades, said an analysis conducted by the American Cancer Society (ACS), released on Tuesday at the World Cancer Congress in Paris. As the global population grows and ages, the highest toll will be among women in poor and middle-income countries, it said, and much of it from cancers which are largely preventable.

*Similar report –*

- [Cancer death among women to rise by 60 per cent by 2030, says study](#) – The Economic Times

**9. [Nationwide chemist One Day Bandh High Court serious on online sales of medicines but Government seems ignorant, says JS Shinde](#) – Business Standard**

All India Organisation of Chemists and Druggists (AIOCD) is an apex body of about eight lakh members involved in sale and distribution of medicines across the country. AIOCD oppose the move of Central Govt. towards regularizing sale of medicines through internet i.e. E-Pharmacy. AIOCD declares Nationwide Chemist BANDH on Wednesday, 23rd November 2016 to attract the attention of Public, Government and concerned authorities towards following important issues. Sale of medicine on internet is totally illegal as per present provision of Drugs and Cosmetics Act 1940 and Rules 1945.

*Similar reports –*

- [Chemists plan bandh on November 23 to oppose online pharmacies](#) – The Economic Times
- [CHEMISTS CALL FOR STRIKE ON NOV 23 AGAINST E-PHARMACIES](#) – Mumbai Mirror

**10. [IMPLEMENTING PPR 2015](#) – Pharmabiz.com**

Pharmacy Practice Regulations was notified in January 2015 by the Central government aimed at regulating and enhancing the status and practice of pharmacy profession in the country. The notification is the first serious attempt to bring comprehensive changes to the outdated provisions in the laws governing the pharmacy practice. The pharmacy practice is currently regulated by two statutes namely the Pharmacy Act and the Drugs & Cosmetics Act notified by the government several decades ago. The PPR 2015 seeks to lay down a uniform code of pharmacy ethics, responsibilities of pharmacist towards patients, job requirements of a pharmacist, role of a community pharmacist, etc.

The new age pharmacists are expected to interact with patients, doctors and nurses in educating the patients in a collaborative care model as is the case with the developed countries. The focus of pharmacy practice in developed countries has shifted from product centric to patient centric with the implementation of modified drug laws favouring patient safety. Whereas in India the pharmacy profession has not received the status and respectability this profession deserves. Pharmacists are more seen by the general public as salesmen handing over medicines prescribed by physicians in the counters of retail chemist shops. Such a perception needs to change in India too for better patient welfare.