1. **Easing clinical trial rules to compromise safety of subjects, say health activists – The Economic Times**

India recently announced a series of steps that may revive clinical research and tests of newly invented drugs here, but health activists say the move may also compromise the safety of the people tested on.

Lauding the decision, the Organisation of Pharmaceutical Producers of India (OPPI), a lobby group of research-based pharma companies in India, said it will expedite the process of clinical trials and create an environment conducive to research and innovation here. The group also welcomed the decision to remove restrictions on hospitals with less than 50 beds to undertake such trials.

Also appeared on:

- Easing clinical trial rules to compromise safety of subjects, say health activists - ETHealthworld.com

2. **US FDA scrutiny on Indian drugmakers to remain intense: Crisil – The Times of India**

Regulatory scrutiny of the US Food and Drug Administration (FDA) for domestic pharmaceutical facilities is expected to remain intense over the medium term, rating agency Crisil said today. The inspection, along with adherence to current Good Manufacturing Practices (cGMP), is critical because outside US, India has the highest number of pharma manufacturing plants approved by the watchdog, it said in a report here.

A majority of ratings that Crisil has assigned to pharmaceuticals companies have not been affected due to this intense scrutiny of the US regulator.

Crisil has ratings on 283 pharmaceutical companies, 55 per cent of which have international presence. Of this, 10 per cent have faced action from the US FDA or other regulators in the developed markets.

Similar news report:

- Pharma companies' profits will moderate in near term: CRISIL – Business Standard
- Most drug makers hold on to their credit ratings despite FDA scrutiny – Mint

3. **NITI seeks public opinion on National Medical Commission Bill – The Economic Times**
   NITI Aayog, government's premier think-tank, has sought public opinion on the draft National Medical Commission Bill, 2016 that would pave the way for replacing the Medical Council of India with a more transparent body to be called as the National Medical Commission. "The idea is to create a world class medial education system that ensures adequate supply of high quality medical professionals, greater emphasis on research, provides for objective periodic assessment of medical institutions, enforces high ethical standards and is flexible to adopt to the changing needs of transforming nation," the Aayog has said in the draft bill. The Committee on the Reform of the Indian Medical Council Act, 1956 chaired by Aayog's vice chairman Arvind Panagariya has sought comments/suggestions/feedback on the draft bill latest by August 31, 2016. Following this, the draft bill will be finalised and would be tabled in Parliament earliest in the winter session.

   Similar news report:
   - NITI Aayog invites public comments on national medical commission bill – Mint

4. **NPPA to cap coronary stent prices - Business Standard**
   The National Pharmaceutical Pricing Authority (NPPA) is in the process of fixing the ceiling price of coronary stents. According to NPPA sources, that there would be two prices for stents - one for plain metal stents and the other for drug-eluting stents. That latter category is more expensive. Stents could be priced anywhere between Rs 25,000 and Rs 1, 25,000.

   Stents were listed by the government as an essential medicine earlier this year when a sub-committee was formed to assess whether coronary stents need to be categorised as essential medicines, which come under the ambit of the NPPA for the purpose of regulating prices.

5. **Pharmexcil swings into action to contain drop in pharma exports – Business Standard**
   Pharma exports in the first quarter of fiscal 2016-17 have come down by 4-5 percent, causing concern among Pharmaceutical Export Promotion Council of India (Pharmexcil) and ministry of commerce and industry, which have convened two meetings this month with top exporters. "In the first three months the growth has not been on expected lines and the ministry is disturbed," Pharmexcil Director GeneralA P. V. Appaji told IANS. The council, which works under the ministry, has called one meeting in Hyderabad on Wednesday and another in Mumbai later this month to look into issues faced by the exporters. The joint secretary in the ministry will interact with CEOs of pharma industries to know what is going wrong and to discuss how to address the problems.

6. **Govt to set up committee to review e-commerce rules – Mint**
   The government has decided to set up a committee to look into all issues including foreign direct investment norms pertaining to the fast growing e-commerce industry in the country. The committee will be headed by the NITI Aayog chief executive officer. The other members in the panel include officials from commerce and industry ministry and department of electronics and IT among others.

   Setting up of this panel also assumes significance as the government has recently permitted 100% FDI in food processing sector. There is also an issues related to e-commerce players selling pharmaceuticals.

7. **Pharmexcil organises seminar to boost export of Ayush products in Europe – Pharmabiz.com**
   To promote Ayush product exports and for the recognition of Ayush as a system of medicine in Europe, the Pharmaceuticals Export Promotion Council (Pharmexcil) has organised a seminar for

the Ayush manufacturers with an aim to create awareness on regulatory guidelines in Europe on August 10, 2016 at Coimbatore.

Seeing the 2nd European World Ayurveda Congress, which will be organised by European Ayurveda Association on October 15-16, 2016 at Koblenz, Germany, as a platform to promote the Ayush medicines in the Europe, the joint secretary of department of commerce has come up with an idea to organise a seminar to create awareness among the Ayush manufacturers about the European regulation.

8. **CDSCO, PvPI to come out with guidelines on good pharmacovigilance practices for Indian cos – Pharmabiz.com**

Central Drugs Standard Control Organisation (CDSCO) and Pharmaco-vigilance Programme of India (PvPI) are jointly framing a set of exhaustive guidelines on par with the existing global guidelines to usher in good pharmacovigilance practices in the country for drug safety.

This comes at a time when the government has mandated the market authorisation holders (MHA) to set up pharmacovigilance (PV) cell in their companies in accordance to the Drugs and Cosmetics Rules, 1945 to collect, process and forward the report to the licensing authority for information on adverse drug reactions (ADRs) emerging from the use of the drug manufactured or marketed by the respective MHA in the country through a gazette notification March 8, 2016.