1. **Budget impact: Drug firms may be forced to market generics, not brands – Business Standard**

The Union Health ministry plans to make prescription of generic medicines mandatory by amending the Drug and Cosmetic rules. The plan to amend the Drugs and Cosmetics Rules to make generic drugs affordable was announced by Finance Minister Arun Jaitley in the Budget. A senior Health Ministry official told Business Standard that once the amendment is in place, drug companies will have to market generic version of drugs instead of brands.

Organisation of Pharmaceutical Producers of India (OPPI), however, said rules are already in place to mandate generic prescription." A Medical Council of India notification of September 2016 mandates every physician to prescribe drugs with their generic names. Further the Drug Technical Advisory Board has also recommended amendment of the Drugs & Cosmetic Rules requiring mention of generic name of the drug on the label in a font size that is two sizes bigger than the trade name. It is in the paramount interest of the patients that stringent quality control systems for manufacturers and effective regulations for the pharmacists are put in place before amending any other law," said Kanchana TK, Director General, OPPI.

2. **Industry gives mixed response on budget 2017-18 – Pharmabiz.com**

Industry has offered a mixed response on the budget 2017-18 and also voiced optimism saying that a silver lining is the increase in the overall outlay for the Ministry of Health and Family Welfare from 2015-16 revised budget of Rs. 7,719 crore to Rs. 11,360 crore for 2017-18. However, there is gaping hole in budget changes pertaining to medical devices and there is no explicit change of current lopsided duty structure that is dis-incentivizing local manufacturing.

Says Kanchana TK, Director General, Organization of Pharmaceutical Producers of India (OPPI), "We had some expectations from the Union Budget 2017-18, given the Government's past stated intentions of improving access to healthcare. Yesterday's World Economic Forum said that that India's public spending on healthcare is much lower than the global average. It is unclear whether the allocations will adequately address current healthcare challenges. We also hoped for some reform announcements on the regulatory front in the form of weighted deduction on R&D, incentives for patents, exemptions of certain duties and taxes etc."

3. **Budget 2017: Boon for patients, bane for Big Pharma – Yahoo News**
   Underlining the need for more generic drugs in the market, Arun Jaitley announced an amendment to the Drugs and Cosmetics Act in his budget speech. "We propose to amend the Drugs and Cosmetic Rules to ensure availability of drugs at reasonable prices, to ensure use of generic medicines," he said. "New rules regarding medical devices will be formulated. These rules will be internationally harmonised and attract investments into this sector. This will reduce the cost of such devices."

   The pharma sector is also unhappy with the lowering of tax on medium and small scale enterprises, something that is likely to give a fillip to the domestic pharma sector.

   Kanchana TK, Director General of the Organisation of Pharmaceutical Producers of India, which represents multinational drug makers, said it was unclear whether the allocations in this year's budget would adequately address India's healthcare challenges. He had hoped for some regulatory reform in the pharma sector, such as incentives for patents, exemption of certain duties and taxes.

4. **Budget plans changes in regulation to reduce prices of drugs and medical devices – The Times of India**
   The Budget may bring good news to patients if proposed changes in the Drugs and Cosmetics Rules, and regulations for medical devices are implemented. The FM proposed amendments in Drugs and Cosmetics Rules to ensure availability of medicines at reasonable prices, and rules for medical devices to reduce costs. The action plan for elimination of diseases like leprosy, measles, filariasis and tuberculosis, availability of additional 1.5 lakh health and wellness centres, and increase in specialist doctors will give an impetus to country's ailing healthcare system. Industry experts feel much more could have been done. "There is no strong thrust or focused measures to bolster the healthcare sector, apart from a mention about improving rural health infrastructure with 1.5 lakh sub centres being upgraded to health and wellness centres and setting up of two more AIIMS" Satish Reddy chairman Dr Reddy's said, adding some amendments have been proposed to the Drugs & Cosmetics Act to provide a fillip for generic medicines, but details need to emerge.

5. **Govt notifies medical devices rules to ease manufacturing – The Hindu Business Line**
   The new Medical Devices Rules, 2017, have been notified by the Ministry of Health and Family Welfare, which will classify devices based on the risks associated with them. Manufacturing of devices are set to become easier, as the government does away with stringent licensing norms. The new rules, which classify devices according to the risk levels, allow the authorities to grant licences without any audit of the manufacturing site for devices with the lower risk. “The manufacturer will, in such a case, be required to do self-certification of compliance with the requirements and based on such certification, the licence will be issued,” an official statement from the Ministry of Health said. The four classes of devices will be based on risk level — low (class A), low moderate (B), moderate high (C) and high (D). At present, only 15 devices are regulated under the classification of drugs. The medical devices industry has been pushing for separate norms for devices.

6. **Medical devices to meet risk proportionate regulatory requirements – Business Standard**
   The Health Ministry has notified the Medical Devices Rule, 2017 in which manufacturers of medical devices will be required to meet risk proportionate regulatory requirements, an official said on Thursday. The new rules framed in conformity with Global Harmonisation Task Force (GHTF) classifies medical devices based on associated risks, into Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk), said a statement. "With a view to bring in the highest degree of professionalism in regulation of medical devices, a system of 'Third Party Conformity Assessment and Certification' through Notified Bodies is envisaged," said the statement. According to the health ministry, the Notified Bodies will be accredited by the National Accreditation Board for Certification Bodies (NABCB). Currently, only 15 categories of medical devices are

regulated as drugs and to that extent, the current regulatory practices in India were not fully geared to meet the requirements of the medical devices sector in the country.

7. **Will govt meet disease eradication targets? – The Hans India**

The Finance Minister announced that the government has action plans to eliminate kala-azar by 2017 and tuberculosis by 2025, among others. Outlining ambitious healthcare plans for the country, Finance Minister Arun Jaitley, in his budget speech, set targets for elimination of crucial communicable diseases.

Previous targets have gone unmet-

- Infant mortality rate to be cut from 39 in 2014 to 28 by 2019
- Maternal mortality rate of 100 by 2020 from 167 in 2013
- 1.5 lakh Health Sub Centres to be Health &Wellness Centres

While it is not clear what the government's action plan will look like, the government has, time and again given targets it finds unable to meet. In September 2014, months after the NDA government took over, the then Health Minister Harsh Vardhan claimed that kala-azar would be eliminated by 2015. He said that AmBisome (amphotericin B) injection, with an efficacy rate of 98 per cent, would be provided free of cost to kala-azar patients.

8. **U.S. House panel to take up bill to spur generic drug development – Reuters.com**

A U.S. House of Representatives subcommittee will take up bipartisan legislation next week to foster generic drug development, the committee's chairman, Representative Greg Walden, said on Thursday. "President (Donald) Trump made it clear ... he wants competition to lower drug prices, and that is precisely what this measure will help accomplish," Walden, a Republican from Oregon, said at a health subcommittee hearing. "Specifically the bill will require FDA (the Food and Drug Administration) to prioritize, expedite and review generic applications of drug products that are currently in shortage, or where there are few manufacturers on the market," Walden said. Trump this week met pharmaceutical executives and called on them to cut prices. He said the government was paying "astronomical" prices for medicines in its health programs for older, disabled and poor people. Walden said recently there had been cases of "bad actors" who "jacked up the price of drugs because there was no competition," but he did not name names. "We want to make sure that does not happen again," the congressman said.

9. **Health ministry notifies Medical Devices Rules, 2017 which will come into force from January 1, 2018 – Pharmabiz.com**

The Union health ministry has notified the Medical Devices Rules, 2017 which will come into force from January 1, 2018. These rules will be applicable to substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i); substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii); and devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940). As per the newly notified rules, medical devices other than in vitro diagnostic medical devices will be classified on the basis of parameters specified in part I of the first schedule, namely low risk as Class A; low to moderate risk as Class B; moderate to high risk as Class C; and high risk as Class D. In vitro diagnostic medical devices will be classified on the basis of parameters specified in part II of the First Schedule, namely low risk as Class A; low to moderate risk as Class B; moderate to high risk as Class C; and high risk as Class D.

10. **Pharma stocks plunge after Jaitley proposes to amend drugs and cosmetics rules – ETHealthworld.com**

Shares of pharmaceutical companies slipped on Wednesday after the Union Finance Minister Arun Jaitley proposed to amend the drugs and cosmetics rules to ensure availability of drugs at

reasonable prices and promote use of generic medicines. Reacting on the announcement, shares of Aurobindo Pharma slipped over 2 per cent in the afternoon trade, followed by Dr Reddy's Labs (down 1.24 per cent), Divi's Labs (down 0.96 per cent), Sun Pharma (down 0.77 per cent) and Cipla (down 0.75 per cent). Glenmark Pharmaceutical, GlaxoSmithKline, Cadila Healchcare and Lupin were also trading lower by 0.48 per cent, 0.26 per cent, 0.10 per cent and 0.05 per cent, respectively, around the same time.