

FROM THE PRESS

Ranbaxy pleads guilty to adulteration charges

In a blow to India's growing reputation as the "pharmacy of the world", the US Department of Justice has imposed fines in civil and criminal cases, up to a total of \$500 million, on Ranbaxy USA Inc, a subsidiary of the Indian pharma major, Ranbaxy Laboratories. The company pleaded guilty to charges of adulteration of drugs produced at its plants in Paonta Sahib and Dewas in India. The Department of Justice has stated that the company admitted that inspections of the Dewas facility by the US Food and Drug Administration (FDA) in 2006 and 2008 found evidence of incomplete testing records, and an inadequate stability programme and manufacturing practices, in breach of regulations. The company also pleaded guilty to making fraudulent statements to the FDA about how it tested drugs at two of its Indian plants.

Meanwhile, Daiichi Sankhyo, which purchased the company from the Singh family, has also filed a complaint against the former owners for non-disclosure of the details of the US investigation before its purchase of the company. To those concerned with access to affordable healthcare for all, this seems a prophecy foretold. If a big drug manufacturer like Ranbaxy can be so negligent in the US market, known for its stringent quality control, one can only imagine the quality of the generic drugs in the Indian market. Also, the silence of the Indian health authorities on the subject is deafening. It is reported that the government has asked the Drugs Controller General's office to re-examine the documents based on which approvals have so far been granted to the company.

PA Francis, Penalty on Ranbaxy. Pharmabiz.com, May 29, 2013 Available from: <http://www.pharmabiz.com/ArticleDetails.aspx?aid=75598&sid=3>

Central scheme for free generic medicines shelved

The much-hyped plan to supply free generic medicines at government health centres and hospitals for one year has been shelved by the health ministry. The scheme, with a planned budget of Rs 6000 crore per year, has been discarded due to financial constraints and the failure to put in place a drug procurement policy over the past 18 months. The states have now been asked to formulate their own schemes for the supply of free drugs and seek funds under the National Rural Health Mission.

The move to make it mandatory for doctors to prescribe drugs by their generic rather than brand names also seems to have fizzled out. The only step taken in that direction so far has been

a circular issued by the Medical Council of India to government medical colleges and hospitals earlier this year, but it had little effect.

The plan to provide free generic drugs was recommended in the report of the high-level expert group (HLEG) appointed in 2011 to look into the Universal Health Coverage plan. The HLEG had found that medicines accounted for 76% of out-of-pocket expenditure on health.

A government official said, "We have neither the kind of resources that a nationwide free drugs scheme requires, nor the infrastructure to ensure glitch-free procurement and distribution of drugs. Attempting something so ambitious without the infrastructure would amount to courting trouble, and even possible litigations. At this moment we can only support states if they formulate their schemes and come to us with adequate facilities for warehousing and an IT-enabled supply chain. Many states have started giving free drugs too."

Abantika Ghosh, Plan for free generic drugs scheme shelved. Indian Express, May 22, 2013 Available from: <http://www.indianexpress.com/news/plan-for-free-generic-drugs-scheme-shelved/1118885/0#sthash.JDEZ5usg.dpuf>

Free medicine scheme in Rajasthan sees more girls getting treatment

A study of the scheme for free medicines being implemented in Rajasthan has revealed that there has been a twofold to threefold increase in the treatment of girl children (0-6 years of age) in the six months since October 2012, when the scheme became operational. The highest increase has been in Jhalawar district, where there has been a threefold rise in the number of girl children in this age group being brought for treatment. In Barmer district, the increase has been 90%-100%. The report says, "In simple terms, now that the medicines are 'free', people are finally flocking to hospitals to avail treatment for their girl children, implying they were not being treated whenever it implied a financial cost."

Dr Hemant Acharya from the organisation, Save the Child, said, "With the government initiative of free medicine, free medical tests, and schemes like the Shubh Laxmi Yojna, people are now willing to bring their girl child for medical attention, which will be a boon to save the female child." Around 10 crore people in the state are reported to have benefited from the scheme in the seven months since its inception.

DNA, Jaipur: "Free" tag brings more girls out for treatment. daily.bhaskar.com, April 10, 2013 Available from: <http://>

daily.bhaskar.com/article/RAJ-JPR-jaipur----free----tag-brings-more-girl-out-for-treatment-4231080-NOR.html

Women health activists hounded

A five-year-old case has been revived against Madhuri Krishnaswami, a health activist working with tribal communities in the district of Barwani, Madhya Pradesh. The court ordered her arrest in connection with a case registered against her and others in 2008 for their protests against corruption in the healthcare facilities of the state. The activist works with the Jagrit Adivasi Dalit Sanghatan and had exposed several instances of corruption in programmes implemented under the Mahatma Gandhi National Rural Employment Guarantee Act. The report mentions that the local officials tried to have her expelled from the area, but failed due to the protests of the citizens. The judge suggested that Krishnaswami apply for bail and when she refused to do so, sent her to jail on 14 days judicial remand. Residents of the area have been staging sit-in protests at six police stations in the district, demanding the immediate release of the activist.

Meanwhile, Soni Sori, an adivasi teacher and activist, has been in jail for over 17 months. She has complained that she was subjected to brutal sexual torture, including having stones forced into her private parts, by the Chattisgarh police in October 2011. Her complaints were reportedly dismissed by the Raipur medical authorities, which claimed that she was "malingering" or feigning illness. It was only after the Supreme Court's intervention that she was re-examined by doctors in Kolkata and treated for her injuries. To add insult to injury, the government of Chattisgarh has now announced that she will be made to undergo a "psychiatric examination."

Groups of women activists nationwide have protested against this as being a malafide move to declare her of unsound mind, thus paving the way for the dismissal of her allegations of police brutality. They have also condemned the statement of a member of the team of the National Commission of Women which visited the activist that Sori was doing fine and only needed psychological counselling. This remark is said to have been the basis of the state government's plan to put Sori through a psychiatric examination.

Kundan Pandey, Activist lands in jail for protesting lack of health facilities in tribal district five years ago. *Downtoearth.org*, May 18, 2013 www.downtoearth.org.in/content/activist-lands-jail-protesting-lack-health-facilities-tribal-district-five-years-ago **Divya Trivedi, Women's groups condemn Chhattisgarh move to declare Soni Sori mentally unsound.** *thehindu.com*, April 13, 2013 Available from: <http://www.thehindu.com/news/national/womens-groups-condemn-chhattisgarh-move-to-declare-soni-sori-mentally-unsound/article4614322.ece>

New MCI board approved

The Medical Council of India (MCI) is to be reconstituted, with former director general of health services, RK Srivastava,

replacing Dr KK Talwar as chairman of the council's Board of Governors.

The medical regulator will have a seven-member board, approved by health minister Ghulam Nabi Azad, and will serve for a term of six months, within which elections will be held and the MCI's original democratic structure restored.

A bill to this effect will have to be passed in Parliament. The government has issued an ordinance for the formation of the new MCI Board of Governors which is to run the medical regulatory body.

The term of the last Board of Governors expired on May 13, making it necessary for the government to issue an ordinance for the formation of a new board to run the MCI until Parliament passes the new Indian Medical Council Amendment Act. The latter provides for the restoration of an elected MCI and fixes the tenure of its president to root out corruption.

Press Trust of India, Govt reconstitutes MCI, ex-DGHS to head Board of Governors. *Business Standard*, May 23, 2013 Available from: http://www.business-standard.com/article/pti-stories/govt-reconstitutes-mci-ex-dghs-to-head-board-of-governors-113052300972_1.html

Quinvaxem vaccination suspended in Viet Nam

The use of Quinvaxem, a vaccine meant to prevent five common, potentially fatal childhood diseases—diphtheria (D), tetanus (T), pertussis (P, whooping cough), hepatitis B (HepB), and haemophilus influenza type b (Hib), was suspended by the Viet Nam ministry of health on May 4. This followed reports of at least nine deaths of vaccinated infants and numerous cases of serious allergic reactions over the preceding six months. The infants had reportedly been in good health before being vaccinated, but suffered convulsions and died soon after vaccination. Several tests were conducted to investigate the matter, but the vaccine was not found to be directly linked with either the deaths or the allergic reactions. Nor was there any evidence to exclude the vaccine as a cause of the adverse effects. The reports say that the cases were from different provinces, and the batches of vaccine were of good quality and met all the requirements.

According to a government spokesperson, 20 out of 42 batches of the vaccine were followed by minor to severe allergic reactions. The spokesman said whole-cell pertussis vaccines, like Quinvaxem, were among those that gave rise to the maximum number of allergic reactions. Now that a decision has been taken to stop using Quinvaxem, the government has to decide on which substitutes can be used to avoid a gap in the immunisation of infants.

Tuoi Tre News, Vietnam suspends Quinvaxem vaccine following 9 deaths. *TuoiTrenews.vn*, May 6, 2013 Available from: <http://tuoiTrenews.vn/society/9330/vietnam-suspends-quinvaxem-vaccine-following-9-deaths>

Patients' right to refuse information

The American College of Medical Genetics and Genomics (ACMG) recently recommended that during genetic sequencing for any medical reason, 57 other specific genes must also be examined for incidental findings, and both the doctor concerned and the patient must be informed of the results. Further, the ACMG clarified that failure to report the information would be considered unethical. The only way a patient can avoid having 57 genes tested is by refusing the gene sequencing altogether.

This step has led to a huge controversy, with Megan Alysse and Marsha Michie of the Stanford University of Biomedical Ethics arguing that while patients have the right to be given information on their health, no one has the right to force information on them if they do not wish to receive it. The ACMG's recommendation has also been attacked on the ground that such testing is very expensive.

"No one should be able to interfere with your ability to accept or decline access. We think that's where these recommendations are problematic, because they do suggest that your physician should interfere in that decision by essentially saying, 'You have to accept this information.' And there is certainly evidence that some people do not want information about long-term health risks, especially in children," say the two researchers.

Cell Press, Patients should have right to control genomic health information, experts say. *Science Daily*, May 9, 2013, Available from: http://www.sciencedaily.com/releases/2013/05/130509123412.htm?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+sciencedaily%2Ftop_news%2Ftop_health+%28ScienceDaily%3A+Top+News+--+Top+Health%29&utm_content=Yahoo%21+Mail

Spinning money from new technologies

A comment in the *Economic and Political Weekly* advises a cautious approach to the media hype about the double mastectomy which the Hollywood actress, Angelina Jolie,

opted for, apparently as a precaution against the threat posed by a genetic predisposition to breast cancer. Media reports have been applauding this step as a brave one and one which will encourage other women to deal with the threat of breast cancer. The writer expresses "an instinctive mistrust of the manner in which modern technology in the last few decades has invaded and displaced all other forms of medical care, creating simultaneously a kind of pseudo-scientific common sense".

Applying this to the Jolie case, she says "the liberal references to percentages", as in the percentage risk of cancer, "without ever clarifying sample sizes, racial or national contexts, or age profiles, is a classic instance of the misuse of statistics. Most reports mention hitherto unheard of genes (except presumably in medical circles) and within a mere 48 hours or so the BRCA gene has achieved a resounding degree of notoriety. The combination of math and science in this fashion, needless to say, is a noxious cocktail. And as a marketing strategy, not entirely unfamiliar." The writer expresses her increasing mistrust of a medical industry that rakes in huge profits by creating anxiety about the possibility of potential health risks. This is discussed in the context of the proliferation of two proven "money spinners": preventive hysterectomies and assisted reproductive technologies.

The comment asserts that while women in particular must be encouraged to take charge of their own bodies, this "cannot happen in the absence of a demand for greater accountability and transparency from the medical scientific empire, whose solutions are invariably industry-driven." It also stresses the need to press governments and the medical establishment to invest in projects aimed at understanding the relationship between food, lifestyle, environment and changing global health trends, and to conduct research in this area.

G Arunima, Refashioning the breast. Modern medicine and dispensable female body parts. *Econ Pol Wkly*, May 18, 2013 Available from: <http://www.epw.in/web-exclusives/refashioning-breast.html>

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