



Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

Bengal Branch

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Editorial

Pharmaceutical innovations like the Novel Drug Delivery Systems (NDDS) present health professionals with a broad range of arsenals to treat diseases with never before efficacy, safety and precision. Clinically the NDDS not only smoothens the saw-tooth pattern of drug levels in blood, but also affords targeting the drugs to their site of action and thus reduces dose-related side effects. Smaller quantity of drug and fewer numbers of dosing could be used to treat a disease with increased success. It is hoped that with more and more research endeavours being focused into this arena, in near future, a large portions of the conventional dosage forms would be replaced by these NDDS and an overall betterment of health care delivery is expected with that change over. Pharmaceutical companies are interested to conduct research on NDDS to get edge over the big pharmaceutical companies to capture the regulated market through ANDA in regulated market. Moreover development and implementation of new branches like Pharmacovigilance will ensure availability of safer medicines to our people. Pharmacoeconomics will provide cost effective health care, which may help to extend the health care to the underprivileged.

Supreme Court of India awards record Rs 6 crore for medical negligence

In a path-breaking judgment, the Supreme Court recently awarded a record Rs 5.96 crore compensation for medical negligence to a US-based NRI doctor, Kunal Saha, who fought a 15-year battle to fasten the charge of gross medical negligence on four doctors and Kolkata's AMRI hospital for the death of his wife Anuradha in 1998.

Until now, courts have been very cautious about fixing liability for medical negligence since the matter is regarded to be technical. But casting away its diffidence and setting a benchmark for future, a bench of Justices Chandramauli Kumar Prasad and V Gopala Gowda enhanced by over 400% the initial Rs 1.73 crore compensation awarded to Saha by the National Consumer Disputes Redressal Commission (NCDRC).

The court held three doctors — Dr Balram Prasad, Dr Sukumar Mukherjee and Dr Baidyanath Halder — guilty of negligence in treating Anuradha, who had contracted a rare skin disease. Prasad and Mukherjee have been directed to pay Rs 10 lakh each to Saha, while Halder will pay Rs 5 lakh. AMRI hospital, where Anuradha's maltreatment took place, would have to pay the remaining Rs 5.71 crore.

The court said the hospital additionally would pay an interest of 6% on the amount from the date of filing of claim by Saha. If the interest is taken to be simple in nature, then the hospital would have to pay another Rs 6 crore. Abani Roy Chowdhury, the fourth doctor involved in the case, died during the pendency of the proceedings.

For Saha, fixing the liability for medical negligence had become a crusade. Even as he went from pillar to post to secure justice, he started an NGO to take up the cause of ethical medical treatment and against excessive/wrong medication by corporate hospitals.

Source: The times of India

Monographs of three products of Supplement 1 to USP 36–NF 31 amended effective from 1st December 2013

- **Valerian**
http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/revisions/valerian.pdf
- **Powdered Valerian**
http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/revisions/powdered_valerian.pdf
- **Powdered Valerian Extract**
http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/revisions/powdered_valerian_extract.pdf

Acarbose may reduce HbA1c about as much as Metformin

Research published online in The Lancet Diabetes-Endocrinology indicated that individuals “with newly diagnosed type 2 diabetes had similar improvement in glycemic control whether treated with acarbose (Precose) or metformin.” Researchers found that following “48 weeks of treatment, the acarbose group had a mean reduction in glycosylated hemoglobin (HbA1c) of 1.11% compared with 1.12% for the metformin groups.” Meanwhile, “a between-group difference of 0.02% was observed after 24 weeks of follow-up.”

Indian Supreme Court rulings freeze clinical trial approvals

Following Supreme Court rulings that blocked as many as 157 clinical trials in 2012, India's Ministry of Health and the Central Drugs Standard Control Organization have effectively stopped reviewing and approving any of the more than 150 pending applications, according to industry officials. Industry expert believes that certainly there is an impact on the business because the normal work has suffered and the Indian industry is losing opportunity.

Pharma sector accounts for 11% of super rich Indians as per Hurun India rich list

Pharmaceutical sector accounted for 11 per cent of super rich Indians, only second to manufacturing sector while Dilip Shanghvi of Sun Pharmaceuticals broke into the top three among the wealthiest Indians, according the Hurun India Rich List.

According to the rich list, prepared by the China-based Hurun Report Inc, Dilip Shanghvi (58) has a personal wealth of \$14,100 million. The founder of Sun Pharmaceuticals, India's second largest drug maker, broke into the top 3 for the first time with a 66 per cent surge in his wealth. This rise in stock price was supported by the expected sales of the cancer drug Doxil, following Janssen Pharma Inc's admission of shortage of the drug supply.

Manufacturing continued to be the main source of wealth in India with 17 per cent of the rich list, followed by pharmaceuticals and real estate, which have both seen their percentages drop slightly to 11 per cent and nine per cent, down from 12 per cent and 10 per cent respectively.

The list has found 141 individuals with US\$ 300m or more, up 41 from last year. Despite a wealth decrease of two per

cent, energy tycoon Mukesh Ambani (56) with a personal asset of \$18.9 billion topped the list. London-based L N Mittal (63), the steel tycoon retained number two position with an asset of \$15.9 billion, according to the second edition of the Hurun India rich list.

Kiran Mazumdar-Shaw (Biocon) came third among the richest Indian women. Desh Bandhu Gupta of Lupin Pharmaceuticals with a net worth of \$3,400 million registered 36 per cent growth in his assets over the year to stand 17 in the list. Likewise, Cyrus Poonawalla of Serum Pharma came 23rd with \$2,600 million assets, after recording a growth of 13 per cent.

Yusuf Hamied of Cipla Pharmaceuticals (\$2,200 million) (26 rank), Pankaj Patel (\$1,900 million) of Cadila Healthcare (rank 29), GV Prasad (\$1,900 million) of Dr Reddy's Lab (rank 29), Ajay Piramal (\$500 million) of Piramal Healthcare (rank 40), Sudhir & Samir Mehta (\$1,400 million) of Torrent Pharma (rank 43), Murali Divi (\$1,200 million) of Divi's Lab (rank 50), Glenn Saldanha & Family (\$1,200 million) of Glenmark Pharma (rank 50), Premchand Godha (\$700 million) of IPCA Laboratories (rank 80), PV Ramaprasad Reddy (\$600 million) of Aurobindo Pharma (rank 96), Hasmukh Chudgar & Family (\$500 million) of Intas Pharma (rank 106), Chirayu R Amin (\$400 million) of Alembic Pharma (rank 107), and Mannalal B Agarwal Family (\$300 million) of Ajanta Pharma (127) are among the super rich Indians.

From the healthcare sector, Prathap Reddy (\$800 million) of Apollo Hospitals with a rank of 77, Habil Khorakiwala (\$700 million) of Wockhardt with ranking of 85 and Dubai-based Azad Moopen (\$400 million) of DM Healthcare with ranking of 114 are in the rich list.

Rare disease research gets more than \$14M boost from U.S. FDA

The U.S. FDA announced on Monday 15 grants worth more than \$14 million for the development of drugs and medical devices for rare diseases. "The FDA is committed to fostering and encoring the development of products for rare diseases, most of which have no available or adequate treatments," said Gayatri Rao, director of the FDA Office of Orphan Products Development. "The grants awarded this year support studies in very vulnerable, difficult-to-treat populations who have no available options." [Drug Store News](#).

Use of plastic bottles to pack liquid medicines under review

In what can have serious implications for the pharma packaging industry as well as drugmakers, usage of plastic bottles to pack pharmaceutical liquid orals and suspensions is under scanner at the moment.

The Drug Technical Advisory Board (DTAB), the apex advisory panel on technical matters under the Union ministry of health, has already constituted an expert committee to examine the matter and will take up the matter for discussion in its next meeting likely to be held in the first week of October.

After a Dehradun headquartered non-profit organisation Him Jagriti made a representation to the Centre suggesting a complete ban on usage of Polyethylene Terephthalate (PET) bottles (both coloured and uncoloured) as primary packaging material in pharmaceutical liquid orals, suspensions and dry syrups as it has severe adverse effects on human health due to the presence of endocrine disruptors, a few months back,

the DTAB decided to constitute an expert committee under the chairmanship of Y K Gupta, professor and head-of-the-department of pharmacology at the All India Institute of Medical Sciences (AIIMS) to inspect the issue and come up with scientific opinion.

The final report is awaited from the expert committee and the matter is likely to be taken up at DTAB's next meeting. A senior official who was present in the last few meetings of the DTAB informed that while formal date is yet to be announced, the next meeting is likely to be held during the first week of October.

Forthcoming Event

One Day Workshop
on
*Clinical Trial: Recent
Development in Science and
Regulation*
18th November 2013

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Indian Pharmaceutical
Association, Bengal Branch
Collaborators:
Apollo Pharmacy
Sanofi Aventis

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