Drug Information Bulletin

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Content

Editorial

Indian Pharmaceutical Association (IPA) recently has taken two steps to strengthen the Pharmaceutical profession in our country. The association has submitted proposal before the Union Government to increase budgetary allocation for different sector of pharmaceutical profession like- More fund for improving infrastructure and manpower of NIPER and Drugs Control administration both state & central, Infrastructure development and training for Pharmacy practice, tax exemption in certain cases for indigenous research & Development etc.

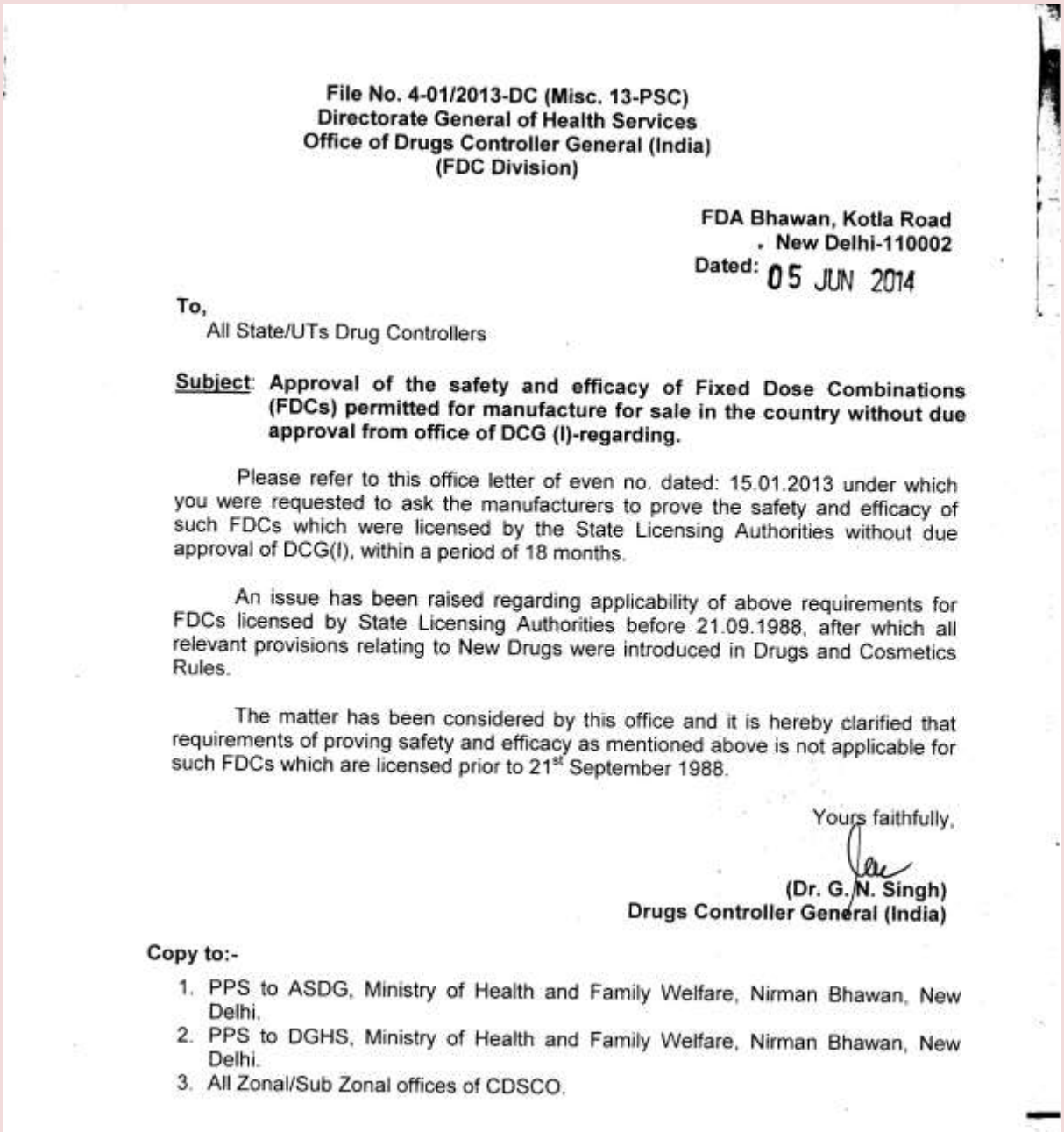
IPA has also submitted memorandum before the 7th Central Pay Commission for improving Pay scales, promotional scopes & other benefits to the pharmacists working in hospital pharmacy, Drugs Control Administration, Laboratories etc. IPA also demanded for creation of Hospital Pharmacy Department, appointment of Deputy Director-Pharmacy under DGHS as per the recommendation of NHRC, creation of Clinical pharmacy services in the big hospitals.

It is a general feeling that though pharmacists are well qualified and trained, they are not been properly utilized in the health care system and not been provided with suitable pay scales, promotional scopes and other benefits. Sometimes scales offered to them are lesser than some of their colleagues who are less qualified and have lesser training.

This move of IPA is highly appreciated by the professionals. It is expected that IPA will continue their endeavor till it is achieved and all professional organizations will join in this movement.

Dr. Subhash C. Mandal
Editor

Safety & Efficacy data of FDCs permitted for manufacturing without due approval of DCGI before 21st September 1988 need not require to be submitted



File No. 4-01/2013-DC (Misc. 13-PSC)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 05 JUN 2014

To,
All State/UTs Drug Controllers

Subject: **Approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)-regarding.**

Please refer to this office letter of even no. dated: 15.01.2013 under which you were requested to ask the manufacturers to prove the safety and efficacy of such FDCs which were licensed by the State Licensing Authorities without due approval of DCG(I), within a period of 18 months.

An issue has been raised regarding applicability of above requirements for FDCs licensed by State Licensing Authorities before 21.09.1988, after which all relevant provisions relating to New Drugs were introduced in Drugs and Cosmetics Rules.

The matter has been considered by this office and it is hereby clarified that requirements of proving safety and efficacy as mentioned above is not applicable for such FDCs which are licensed prior to 21st September 1988.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to:-

1. PPS to ASDG, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. PPS to DGHS, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
3. All Zonal/Sub Zonal offices of CDSCO.

EU regulators to reinstate approval for Ranbaxy's Toansa manufacturing facility

European regulators will reinstate the GMP certificate for Ranbaxy's Toansa manufacturing site in India after the company implemented corrective measures. The facility's GMP certificate was suspended in January following an inspection by the FDA that identified deficiencies at the plant.

In response to the FDA findings, the EMA sent a team of inspectors, who were joined by others from Switzerland and Australia, to complete an unannounced inspection of the facility. The agency said

that although the inspection team uncovered a number of deficiencies at the site, it was concluded that there was no evidence that any drugs on the EU market containing an active pharmaceutical ingredient manufactured at the Toansa site were of "unacceptable quality or presented a risk to the health of patients."

The EMA added that it is satisfied that the corrective measures put in place by Ranbaxy are sufficient to ensure GMP compliance at the facility. However, the agency indicated that regulators in Europe "have identified the need to keep the Toansa site under close supervision and this will be done in collaboration with India and other regulatory authorities around the globe."

Ref: Business Standard

Chicago accuses painkiller-makers of deceptive marketing and sues

The City of Chicago has filed suit against five of the world's largest narcotics manufacturers, accusing the companies of concealing the health risks associated with a class of potent painkillers in order to boost profits.

Filed in Cook County Circuit Court on Monday, the suit contends the drugmakers violated city ordinances and other laws against false advertising, conspiracy, insurance fraud and consumer fraud by "knowingly and aggressively" marketing opioids such as OxyContin as "rarely addictive" and touting benefits that "lacked scientific support."

The companies named in the suit – Actavis, Endo Health Solutions Inc., the Johnson & Johnson unit Janssen Pharmaceuticals, Purdue Pharma LP and Teva Pharmaceutical's Cephalon Inc. -- used such deceptive marketing tactics to encourage doctors to prescribe and patients, including veterans and the elderly, to purchase more of these painkillers, leading to a rise in the "misuse and abuse" in the drugs.

The result has been an increase in addiction and overdose that "plagues communities in Chicago and other cities across the country," and has contributed to rising health care costs and an uptick in emergency room visits, the suit alleges.

The city is seeking to recover all or part of the $9.5 million for 400,000 prescriptions for these drugs it paid to fill since 2008, compensation for damages allegedly caused by the drugs, additional civil penalties related to alleged fraud and all attorneys fees and court costs.

Chicago is not seeking to ban the drugs, all of which are approved by the U.S. Food and Drug Administration.

Painkillers were involved in more than 16,500 deaths in the U.S. in 2010, the latest year for which data was available, according a 2013 analysis from the federal Centers for Disease Control and Prevention.

Ref. Chicago Tribune

DNDi Welcomes Progress Made at WHA in R&D Financing and Coordination for Developing Country Health Needs

Overall political consensus and initial financial commitments secured during recent World Health Assembly, laying foundations for publicly-led research and development to bridge innovation of and access to essential health tools in developing countries [Geneva, Switzerland - 3 June 2014] - At

the recent 67th World Health Assembly (WHA) in Geneva, a global political consensus by the Member States gave a solid 'go-ahead' to advance a process that began over a decade ago to ensure that research and development (R&D) for the priority health needs of developing countries benefits from global public leadership. The process, referred to as the Consultative Expert Working Group (CEWG) process, notably aims at securing sustainable financing and coordination to fundamentally link innovation and access to essential health tools. Initial financial commitments were announced by France, Switzerland, Brazil, and Kenya. During the Assembly, Member States adopted a decision, which:

- Notes progress made, notably the four 'demonstration projects' selected and initiated, and requests progression of the four additional demonstration projects in the selection list;

- Calls for indicators to measure innovative aspects of the projects, including financing, use of open access models, multi-sectoral research platforms, and delinkage, among others;

- Requests the WHO Secretariat to explore the establishment of a pooled fund for voluntary Member State contributions, potentially to be hosted by the Special Programme for Research and Training in Tropical Diseases (TDR), stipulating that it cover R&D for type III diseases (those primarily affecting developing countries), type II diseases (occurring in developed and developing countries but affecting the latter in substantially greater proportion), and the specific R&D needs of developing countries in relation to type I diseases (occurring equally in developing and developed countries). It also stipulated that Member States play a role in the governance of the funding mechanism. 'We welcome the commitment of Member States to move this process forward by exploring a pooled funding mechanism, implementing demonstration projects, and creating an R&D observatory to help determine global health R&D priorities', said Dr Bernard Pécoul, Executive Director of DNDi. 'This is a major step forward, one that we hope will help to build a global framework to sustain innovative approaches to addressing the market and public health policy failures that have left neglected patients without adequate treatments.'Since its creation in 2003, DNDi has advocated for increased public responsibility and a more enabling environment in which to carry out patient needs-driven R&D. DNDi decided to propose two demonstration projects to the WHO CEWG process, including the selected project: 'The Visceral Leishmaniasis Global R&D and Access Initiative'. Through its implementation, DNDi aims to demonstrate that coordination, transparency, capacity building, and innovative research and financing incentives can boost development and delivery of treatments for patients in need, and also ensure that the cost of treatments is not linked to the investment made in their development. The interim outcomes will be examined in 2016, at an open-ended meeting of Member States prior to the 69th WHA.

Ref. Ip-health

Forthcoming Event

ISPOR 6th Asia Pacific Conference
6th - 9th September 2014
Beijing International Convention Centre, Beijing, China
Early Registration Deadline: 22nd July 2014
Registration Cancellation Deadline: 22nd July 2014
Edit Registration Deadline: 11th August 2014