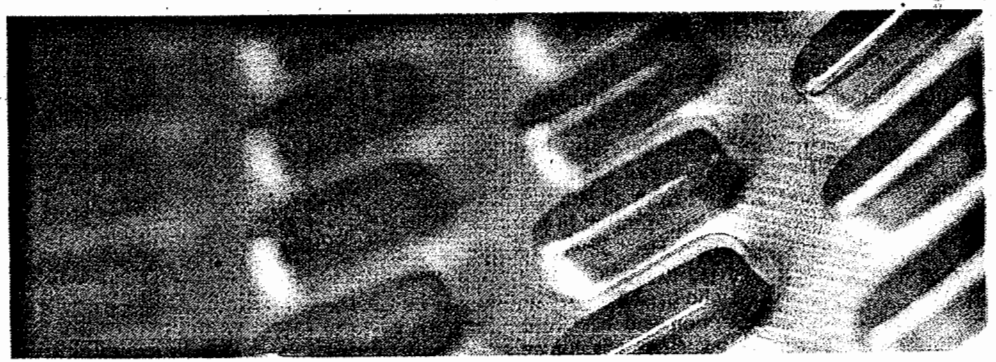
PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Business Line, Delhi
Saturday 12th April 2014, Page: 3
Width: 22.73 cms, Height: 13.59 cms, a4r, Ref: pmin.2014-04-12.36.31

Regulator starts examining the safety of combination drugs

Asks manufacturers to submit data to central regulator, not State-level entities



AESHA DATTA
New Delhi, April 11

The drug regulator's fight to weed out potentially unsafe combination drugs is picking up pace. The Central Drugs Standards and Control Organisation which is headed by the DCGI, has started examining the safety of fixed-dose combination drugs, which are formulations used for a variety of medicines ranging from antibiotics to painkillers.

The CDSCO, which intends to regularise this segment, wanted both small and large manufacturers to get its approval. But, despite the directive, many continued to get it done at the local level. Some of the known FDC manufacturers include smaller entities such as Restech Pharma, Naxpar Pharma, Unix Biotech, as well as big names like Cipla.

The Drug Controller General of India has once again asked Drug Controllers at the State and Union Territory level to inform all manufacturers of fixed-dose combination drugs that they need to make presentations regarding the safety and efficacy of their drugs before the Central regulator, DCGI GN Singh told *Business Line*.

All such manufacturers, whose drugs had not received approval from the DCGI earlier, are required to submit relevant data and applications before the CDSCO before end of August, Singh said.

Expert panels

According to a circular sent to the State and Union Territory Drug Controllers, the manufacturers are expected to submit published data regarding safety and efficacy of the drugs, original data generated by the manufacturers, and the regulatory status of the drugs in other countries, along with original pack and package inserts.

The DCGI office has also constituted 10 expert committees to examine the applications being received.

FDC drugs, which are considered new drugs, were brought under the ambit of the DCGI in May 2002. The DGCI was given the authority to grant permissions/licences for these new drugs under Rule 122 of the Drugs Act.

In this regard, the DCGI had first sent notices to FDC manufacturers in January last year, asking for safety and efficacy data to be examined by experts.

However, many manufacturers had challenged this order legally, calling it arbitrary.

In December 2013, the Punjab and Haryana High Court stayed an order by the DGCI , while in October the Himachal Pradesh High Court had also put a stay on this order.

However, Singh said that there was "no stay on examining the safety issues." The Ministry of Health and Family Welfare has not been able to get the court stay vacated as yet.