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Govt moves to finalize methodology to fix prices of new drugs

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Teena Thacker





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The department of pharmaceuticals has called a meeting with industry representatives on 31 October to discuss the proposed changes in the Drug Prices Control Order 2013. Photo: Hemant Mishra/Mint

The government has initiated the process to finalize a new methodology to fix the prices of new drugs amid concern over delays in approving prices, a pre-requisite for launching a new drug.

The government is considering doing away with the present practice of deciding a new price for each applicant of “new drug”, according to people in the government who are privy to the development.

The department of pharmaceuticals (DoP) under the chemicals ministry has called a meeting with industry representatives on 31 October to discuss the proposed changes in the Drug Prices Control Order (DPCO) 2013.

About 200 new drug applications are pending, some as old as 1.5-2 years, according to the people cited above.

While drug pricing watchdog National Pharmaceuticals Pricing Authority (NPPA) governs price control, DPCO is the order by which price control is enforced.

DPCOs are issued by the chemicals ministry and issued under the Essential Commodities Act, 1955, through which certain medicines could be declared as essential commodities and their prices capped. The National List of Essential Medicines (NLEM), issued by the ministry of health and family welfare, forms the basis of deciding which medicines should come under price control via DPCO.

According to one of the proposed amendments, the government is contemplating a schedule of DPCO to contain only the medicine's name in the NLEM without referring to the strength and dosage which shall be liable for price cap in a bid to reduce time needed for government approval.

D.G. Shah, secretary general of the Indian Pharmaceutical Alliance (IPA), which represents 20 of the country's biggest drug makers, said DPCO 2013 should be given a reasonable period to evaluate its impact on access to medicines at affordable prices.

Tweaking the definition of "new drug" and eliminating differentiation between Ceiling Price and Retail Price, will enable the NPPA to treat all "New Drugs" as Scheduled Products. As per the proposed amendment, even products which are non-scheduled under the DPCO 2013 would become Scheduled Products and will get covered by Ceiling Price, instead of retail price. This will force the companies to reduce their prices, said Shah.

Consequently, not many companies will go for new introductions and this would stunt the growth of the industry, he said.

The IPA's analysis is based on Pharmatrac data that showed that the share of NLEM products by volume has increased from 17% in June 2014 to 24% in December 2016. The volume of NLEM products (+7%) has grown at more than twice the rate of growth for the total pharmaceutical market (+3%) as per Moving Annual Turnover (MAT) December 2016.



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“This shows that the DPCO 2013, unlike in the past, has led to increase in production volume of price-controlled medicines,” Shah added.

The government has also proposed that DPCO will include only ‘off-patent’ medicines in its schedule and hence in-patent medicines will not be subject to price ceiling by NPPA.

“They can be regulated through compulsory licensing under the Patents Act or by use of emergency powers under paragraph 19 of DPCO-2013, that too, only when expressly directed by the government in the Department of Pharmaceuticals to do so,” the department had proposed in its draft pharmaceuticals policy.

The All India Drugs Action network (AIDAN), a group of healthcare focused NGOs, said the process is “neither transparent nor inclusive”. According to AIDAN’s representative, “Public health groups have strategically been excluded from the meeting scheduled for Tuesday. No draft of the amendments has been circulated”.

AIDAN has filed a public interest litigation in the Supreme Court to challenge the rationale of the pricing mechanism of the DPCO.

“The Supreme Court has instructed to file an affidavit to explain the shift from cost-based pricing to market-based pricing as it appears to be “irrational” and provides “room for abuse”, the AIDAN representative said.

“DoP is subverting the court process by undertaking amendments which have little bearing on affordability for the poor and are meant,



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almost exclusively, to address industry grievances”, the representative said.

The meeting on Tuesday will be attended by pharma lobby groups including Indian Drug Manufacturers’ Association, Indian Pharmaceutical Alliance, Federation of Pharma Entrepreneurs, Organisation of Pharmaceutical Producers of India, Bulk Drugs Manufacturers Association of India, top industry bodies like Confederation of Indian Industry (CII), trade body Federation of Indian Chambers of Commerce and Industry (Ficci) , Associated Chambers of Commerce and Industry of India (Assocham), PHD Chamber of Commerce and Industry, American Chamber of Commerce in India, and lobby body Healthcare Federation of India (NAThealth), among others.

<http://www.livemint.com/Industry/RddH0wXp6Q4sH1E3qaPsyK/Govt-moves-to-finalize-methodology-to-fix-prices-of-new-drug.html>

Business Standard

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<http://www.business-standard.com>

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ANI | New Delhi [India] Last Updated at October 25, 2017 15:42 IST

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Mr. Yamada further said, "Under the technical training programme nearly 10 trainees will be engaged from Indian medical organisation in December, 2017. We will arrange some visits to diagnostic labs and medical organisations."

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(This story has not been edited by Business Standard staff and is auto-generated from a syndicated feed.)

http://www.business-standard.com/article/news-ani/japanese-health-ministry-funds-programme-for-technical-personnel-exchange-in-diagnostic-sector-117102500597_1.html

Konoike Transport : Japanese Health Ministry funds programme for technical personnel exchange in diagnostic sector

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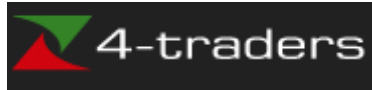
10/25/2017 | 08:25pm EDT

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<http://www.4-traders.com/KONOIKE-TRANSPORT-CO-LTD-12786978/news/Konoike-Transport-Japanese-Health-Ministry-funds-programme-for-technical-personnel-exchange-in-dia-25359905/>



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<https://www.aninews.in>



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<https://www.aninews.in/news/business/business/japanese-health-ministry-funds-programme-for-technical-personnel-exchange-in-diagnostic-sector201710251535150005/>

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<http://ashokanews.com/2017/10/25/japanese-health-ministry-funds-programme-for-technical-personnel-exchange-in-diagnostic-sector-1508926092218307/>

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[NEWS AGENCIES](#) | Updated on: 25 October 2017, 16:22 IST



(ANI)

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-ANI

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<http://htsyndication.com/htsportal/asian-news-international/article/japanese-health-ministry-funds-programme-for-technical-personnel-exchange-in-diagnostic-sector/23784238>

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By [ANI FeedsEmail](#)

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<http://www.newkerala.com>

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- 15 hours ago
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<http://www.newkerala.com/news/fullnews-283170.html>

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**COMMENT**

New Delhi [India] | October 25, 2017 12:01:13 AM IST

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primitive stage. Huge potential exists in diagnostic technologies sector in India. Japan is a big success story and we, in Japan, need to exchange our knowledge and collaborate to move to the next level.

"Healthcare in India is growing at a very fast pace. It is expected to be USD 280 billion in size by 2020, growing at a compound annual growth rate of 16 per cent. According to Reports, the medical devices market is estimated to grow organically at 15 percent to USD 8.6 bn by 2020. (NATHEALTH - Deloitte Report). Lots of new hospitals are opening and healthcare has taken a tremendous leap in service standards. Hence, the supply chain needs to be strengthened to meet the growing demand," Amano added. (ANI)

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Japanese Health Ministry funds programme for technical personnel exchange in diagnostic sector



New Delhi [India], Oct 25 : To address diagnostic technological differences between India and Japan, a programme approved by the Ministry of Health, Labour and Welfare in Japan is introduced in India and is funded by "The International Promotion of Japan's Healthcare Technologies and Services in 2017" conducted by the National Center for Global Health and Medicine under the Ministry of Health, Labour and Welfare, Japan.

The programme "Technical Training for Materializing International Diagnostic Business in India" will be conducted by National Centre for Global Health and Medicine (NCGM) which has been approved and appointed by Ministry of Health, Labour and Welfare in Japan.

The programme which will be taken forward by Japanese majors in diagnostic technologies- Konoike Transport and J-VPD, Inc. is also being supported by Embassy of Japan in India and Delhi Medical Association. The programme is part of Japan's government efforts to push and promote its Healthcare Technologies and Services globally. Hence, the Ministry of Health, Labour and Welfare provides financial support to the programme.

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Tetsuji Yamada, President, J-VPD, Inc. highlighted Japanese Diagnostic technology and know-how to India and explained how to utilise the diagnostic outsourcing in Japan.

"Indian demand for the medical and diagnostic industries is expanding rapidly. However, still there are many major issues to be solved which are test accuracy, quality, cost and lead-time control of transportation due to lack of technologies, manpower and facilities in the sophisticated area of Genetic testing or Chromosome inspection," he added.

Mr. Yamada further said, "Under the technical training programme nearly 10 trainees will be engaged from Indian medical organisation in December, 2017. We will arrange some visits to diagnostic labs and medical organisations."

Minoru Amano, Executive Officer, and General Manager of Medical Business Division, Konoike Transport Co., Ltd. said, "India's healthcare sector is witnessing a double digit growth. But the supply chain is still in its primitive stage. Huge potential exists in diagnostic technologies sector in India. Japan is a big success story and we, in Japan, need to exchange our knowledge and collaborate to move to the next level.

"Healthcare in India is growing at a very fast pace. It is expected to be USD 280 billion in size by 2020, growing at a compound annual growth rate of 16 per cent. According to Reports, the medical devices market is estimated to grow organically at 15 percent to USD 8.6 bn by 2020. (NATHEALTH - Deloitte Report). Lots of new hospitals are opening and healthcare has taken a tremendous leap in service standards. Hence, the supply chain needs to be strengthened to meet the growing demand," Amano added.

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