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Industry urges govt to defer revision of NLEM till mid-2021 citing COVID-19 pandemic

Shardul Nautiyal, Mumbai

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The pharmaceutical industry has urged the Central government to defer revision of National List of Essential Medicines (NLEM-2015) until second quarter of 2021 citing COVID-19 pandemic crisis.

At a stakeholder consultation meet held by the Indian Council of Medical Research (ICMR) on revision of NLEM-2015, industry has strongly recommended to government consultative committee to consider essentiality as the main criteria and not its turnover for a drug to be listed in NLEM-2015. Notified in 2015 and implemented in 2016, NLEM-2015 includes all the drugs that fall directly under the government's price regulation mechanism. Plans are ongoing to revise the NLEM with special focus on adding drugs used to treat cancer, diabetes and thyroid.

Prof Y K Gupta, vice chairperson of the Standing National Committee on Medicines (SNCM) — a panel constituted by the ministry of health and family welfare to revise NLEM — chaired the meet on August 17. Dr Vijay Kumar, head, basic medical sciences division of ICMR, A K Pradhan, deputy drug controller from Central Drugs Standard Control Organization (CDSCO) and Dr Nilima Kshirsagar, national chair clinical pharmacology, ICMR, also attended the meeting.

During the virtual meet, the industry stakeholders cited issues related to streamlining supply chain and efforts to avoid drug shortages due to COVID-19. During the meeting, industry stakeholders also raised issues like specific medicine strengths and dosages should be mentioned in the list, only one drug should be incorporated in each category, patented drug should be excluded from the list, only DCGI-approved drugs should be part of the upcoming NLEM list, sustained-release drugs should be specifically mentioned in the list and some high priced drugs like cancer medicines which were already under trade margin rationalisation should not be further included in the upcoming NLEM list.

Indian Drug Manufacturers' Association (IDMA), Indian Pharmaceutical Alliance (IP Alliance), US-India Business Council (USIBC), US-India Strategic Partnership Forum (USISPF) and Organisation of Pharmaceutical Producers of India (OPPI) attended the meet.

Regulated by National Pharmaceuticals Pricing Authority (NPPA) NLEM list includes all the formulations, which fall directly under the government's price regulation mechanism. The manufacturer cannot randomly increase prices without prior approvals. Using Para 19 of the Drug Price Control Order, 2013 — the law that governs the pricing of medicines in India — the central government expands the price control mechanism. The rates of drugs included under the NLEM are capped on the basis of their ceiling prices, which are calculated by taking the simple average of all drugs falling under the same category, but with market share of at least 1 per cent. For other drugs — which are not included in the NLEM — the manufacturers can raise the prices by up to 10 per cent every year.

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