GOVERNMENT OF INDIA HEALTH AND FAMILY WELFARE LOK SABHA

UNSTARRED QUESTION NO:3126 ANSWERED ON:15.03.2013 ESSENTIAL DRUGS Dhanaplan Shri K. P.;Shanavas Shri M. I.;Singh Shri Bhupendra ;Viswanathan Shri P.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of the principles for determining the essentiality of a drug and the guidelines laid down by the Government to select medicines for inclusion in the National List of Essential Medicines (NLEM);

(b) whether the Government proposes to revise the NLEM and has constituted a committee for the purpose;

(c) if so, the details thereof indicating the composition and the terms of reference of the said committee including the criteria therefor;

(d) whether the Supreme Court has recently expressed unhappiness over the delay in preparation of revised list of essential drugs; and

(e) if so, the details thereof along with the corrective measures taken/proposed by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) to (e) The objective of the National List of Essential Medicines (NLEM) is that the drugs included in it are adequate to meet the common contemporary health needs of the general population of the country. It is one of the key instruments in balanced healthcare delivery system of a country. It is the general obligation of the health administrators to ensure abundant availability of these drugs in the country. The primary purpose of NLEM is to promote rational use of medicines considering the three important aspects i.e. cost, safety and efficacy. Furthermore, it promotes prescription by generic names. It is revised and updated from time to time in the context of contemporary knowledge of use of therapeutic products. The first NLEM was prepared and released in 1996. This list was subsequently revised in 2003.

To address the issues of changing disease prevalence, treatment modalities, introduction of newer medicines and identification of unacceptable risk-benefit profile as well as therapeutic profile of some medicines, a Core Committee of Experts from various subjects specialities was constituted by the Ministry of Health and Family Welfare by Order dated 6th July, 2010 under the chairmanship of Dr. Y.K. Gupta, Professor and Head, Department of Pharmacology, AIIMS, New Delhi, to update the NLEM, 2003. The Core Committee obtained the opinion/views through a "National Consultation Meet for Revision of National List of Essential Medicines" organized by the Department of Pharmacology, AIIMS and the Central Drugs Standard Control Organization (CDSCO) on December 3-4, 2010. Experts from different disciplines from medical and pharmaceutical institutes and hospitals from across the country and concerned Government agencies participated. The recommendations of the Workshop were further deliberated upon by the Expert Core Committee on 4th January, 2011 and 31st January, 2011 at CDSCO and the NLEM, 2011 was finalized.

The NLEM, 2011 contains 348 medicines belonging to 27 therapeutic categories such as antineoplastic, anti-cancer, immunological, anti infective Cardiovascular, ophthalmological preparations, Diuretics, anti-allergic etc. Medicines have also been categorized based on essentiality at different levels of healthcare viz.

(i) 181 Medicines for Primary (P), Secondary (S) and Tertiary (T) healthcare.

- (ii) 106 Medicines for Secondary(S) and Tertiary(T) healthcare
- (iii) 61 medicines for Tertiary (T) healthcare.

No committee has been constituted to revise NLEM after 2011. The Government has no information that the Hon'ble Supreme Court has made any observation over the delay in the preparation of revised list of essential drugs.