GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
STARRED QUESTION NO.179
TO BE ANSWERED ON THE 29TH NOVEMBER, 2019
NATIONAL ESSENTIAL DIAGNOSTICS LIST

***179. SHRI PASUNOORI DAYAKAR:**
SHRI VENKATESH NETHA BORLAKUNTA:

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

(a) whether the country has got its first National Essential Diagnostics List (NEDL) by ICMR which aims to bridge the current regulatory system's gap that do not cover all the medical devices and in-vitro diagnostic device;

(b) if so, the details thereof along with the views of general public and experts in this regard;

(c) whether it is a fact that while affordability of diagnostics is a prime concern in countries like India, low cost, inaccurate diagnostics have made their way into the Indian market which could adversely affect the quality of healthcare system, if so, the details thereof and the reaction of the Government thereto; and

(d) whether implementation of NEDL would enable improved healthcare services delivery through evidence-based care, improved patient outcomes, reduction in out-of-pocket expenditure, effective utilisation of public health facilities, effective assessment of disease burden, disease trends, surveillance/outbreak identification and address antimicrobial resistance crisis, if so, the details thereof and results yielded so far?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)

(a) to (d): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 179* FOR 29TH NOVEMBER, 2019

(a)to(d) The Free Diagnostics Service Initiative (FDI) was rolled out under the aegis of National health Mission in July, 2015. It encompasses three components – Free Laboratory services; Free Teleradiology Services and Free CT scan services. The Essential Diagnostics list mandating the provision of identified diagnostic services at different level of public healthcare institutions was notified under NHM in July 2015. The EDL is reviewed and revised from time to time. Recently, the Guidance document for implementing Free Laboratory services has been released to States/UTs in July 2019 and the EDL has been expanded. The notified EDL under NHM provide for 134 tests at District Hospital, 111 tests at Sub District Hospital, 97 tests at Community Health Centre, 63 tests at Primary Health Centre and Ayushman Bharat Health & Wellness Centre - PHCs; and 14 tests at Sub Centre and Ayushman Bharat Health & Wellness Centre – Sub Health Centre. The tests are identified keeping in view the needs for providing comprehensive Primary Health Care inclusive of Reproductive & Child Health, control of communicable and Non Communicable diseases, specially related to National programmes and Initiatives implemented under NHM.

The National Essential Diagnostics List (NEDL), published by ICMR, builds upon the Free Diagnostics Service Initiative of NHM and suggests the list of essential diagnostics tests to be performed at each facility level. The NEDL is in public domain and available at https://www.icmr.nic.in/sites/default/files/guidelines/NEDL_2019.pdf.

The draft ICMR - NEDL was put up for public comments on December 14, 2018. The comments and suggestions were received from pharma associations, NGOs, diagnostic manufacturing companies, and independent experts. The comments/suggestions are indicated as per Annexure. The suggestions received were discussed with the expert group comprising of representatives of national program (TB, Malaria, HIV/AIDS, Hepatitis, Non-Communicable Diseases), NHSRC and experts (clinicians, microbiologists and pathologists). The suggestions approved by the group were incorporated in the final NEDL document.

The In Vitro Diagnostics are regulated under Drugs and Cosmetics Act, 1945 and Medical Devices Rules, 2017 for their manufacture, import, sale and distribution. Before placing any In Vitro Diagnostics in the market, it has to comply

with the various regulatory requirements like submission of data pertaining to its development, manufacturing, quality, stability, performance, testing and quality management system under which it is produced. Accordingly, there are regulatory measures to safeguard the quality of In Vitro Diagnostics. The manufacturers, importers and distributors who do not comply with these requirements are punishable under the Drugs and Cosmetics Act, 1940. No reports that low cost inaccurate diagnostics have made their way into the Indian market which could adversely affect the quality healthcare system have been received in Central Drugs Standard Control Organization (CDSCO).

The EDL notified under NHM is comprehensive and includes suggestions contained in NEDL of ICMR. The implementation of Free Diagnostics Service Initiative aims at reducing Out of Pocket Expenditure and ensuring quality diagnostics services.

Annexure

Comments received from general public and experts

- National EDL should be strategic, realistic and address the key demands of our country.
- Ability to deliver at multiple levels of health care, with a focus on primary health care, is a very important criterion for the national EDL.
- The list should have tests for both communicable and non-communicable diseases (NCDs), complimenting the national vertical health programmes.
- NEDL should be small, simple, robust, relevant and affordable to society.
- It should provide guidance on logistics and infrastructure, maintaining quality and supply chain.
- There is a need to build capacities of service providers in guiding patients which facilities offer what diagnostics tests, collection of samples at spokes and transport of samples to hubs.
- National EDL should ensure minimal movement of patient across facilities and providers.
- An innovative research in diagnostics related to our priority healthcare conditions was emphasized.
- Assay formats need to be discussed for cost-effectiveness considerations.
- Innovations are needed to bridge gap between rapid test and central laboratory tests.
- The necessity of point-of-care tests for common pathogens was emphasized.
- Inclusion of culture facilities in the list specifically for quality of healthcare and antimicrobial resistance was highly recommended.
- There is a need to ensure quality of products and tests for diagnosis – a well defined in-house validation and evaluation criteria are important.