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

LOK SABHA
UNSTARRED QUESTION NO. 1110
TO BE ANSWERED ON 18TH SEPTEMBER, 2020

FAULTY COVID-19 TEST KITS

1110. SHRI HIBI EDEN:
SHRI THIRUNAVUKKARASAR SU:

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

(a) whether the Government has imported huge quantity of COVID-19 antibody testing kits from China, if so, the details thereof;

(b) the sequence of incidents which led the Government to withdraw the faulty COVID-19 antibody test kits from China and the grounds on which the import orders from China were cancelled;

(c) whether there exist any complaints against massive profiteering and over-pricing in kits imported from China, if so, the details thereof;

(d) whether the Government has taken any action or proposes to take any action against the persons involved in this serious lapse, if so, the details thereof; and

(e) the steps taken by the Government to ensure availability of genuine testing kits to combat the disease?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) ICMR placed purchase orders to Indian firms which were cancelled subsequently without any payment to any Chinese company. ICMR has not imported huge quantities of antibody test kits from China.

(b) Antibody kits of M/s Aark pharmaceutical (Woldfo) and M/s Gene2me (Livzon) were sent to field. When complaints were received from states of Rajasthan, Punjab, Karnataka regarding non-performance of the Antibody test kit in the field, and based upon the said feedback from the field, those purchase orders were canceled without any payment. Simultaneously, the licenses of these companies were also cancelled by Drug Controller General.

(c) ICMR has informed that they have not received any such complaint. However, a public grievance was received primarily describing a commercial dispute amongst different distributors of the kits supplied by Woldfo company, China. ICMR is not a party to said dispute amongst different distributers of a commercial entity. As there was no payment made by ICMR to any supplier, there was no further action to be taken by ICMR.

(d) Seventeen (17) importers were issued licenses in Form MD-15 between 26.03.2020 and 22.04.2020 for import of Antibody Rapid Diagnostic Kits from China under Medical Devices Rules,2017 subject to various conditions.
ICMR reported that the above said Test Kits do not meet the specification in the field and issued order on 26.04.2020 cancelling the Purchase Orders.

Pursuant to above information from ICMR, the importers were issued directions on 28.04.2020 to stop import of the said diagnostic kits as well as they were asked to show cause as to why action will not be taken to suspend or cancel their licenses. Subsequently, on 29.04.2020, after verification of the responses, as received, the importers were directed that no batches of the said Diagnostic kits should be imported for sale/ stock/ distribution or be sold or offered for sale and entire batches imported and supplied, should be recalled from the market including hospitals and accordingly, their import licenses were made infructuous and cancelled with immediate effect.

(e) Detailed requirements & conditions of the manufacturing/import license required to be complied by the licensee are prescribed in the MDR 2017.

In addition to above, following steps have been taken to ensure availability of quality COVID-19 In-vitro Diagnostic Kits and reagents combat the disease in the country.

ICMR in co-ordination with CDSCO has issued Guidelines for Validation and batch testing of COVID-19 diagnostic kits & for validation centres.

Acceptance criteria for COVID-19 diagnostic kits & regents has been fixed by the ICMR Experts group for testing product and quality at the ICMR designated labs to ensure the quality of the product for recommendation to use in the country for testing patient samples.