

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

**LOK SABHA
UNSTARRED QUESTION NO. 4458
TO BE ANSWERED ON 20TH MARCH, 2020**

AFFORDABLE DRUGS

4458. SHRI PRATAPRAO JADHAV:

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

- (a) whether the Government has emphasized the need of affordable drugs to the BRICS countries, if so, the details thereof;
- (b) whether the BRICS countries are considering to sign a Memorandum of Understanding (MoU) for giving mutual consent, sharing information on matters of health related emergency situations on international and national level and to speed up the process to get regulatory approval;
- (c) if so, the details thereof; and
- (d) whether the BRICS nations have accorded consensus on draft MoU for regulatory cooperation for improving standards, certification process and regulatory mechanisms for drugs and pharmaceuticals and for promoting secured, effective, affordable and quality drugs, if so, the details thereof?

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

(a) to (d): Cooperation in the field of medical products regulation, facilitates access to safe, affordable efficacious and quality medical products. Draft Memorandum of Understanding (MoU) has been circulated amongst BRICS countries.

Draft Memorandum of Understanding (MoU) covers cooperation in the field of the regulation of Medical Products for human use in various areas like:

- i. Medical products regulation;
- ii. Clinical Trial regulation;
- iii. Medical Devices regulation;
- iv. Regulation of Active Pharmaceutical Ingredients (APIs);
- v. Regulation of biological products;
- vi. Pharmacopoeia;
- vii. Quality of Medical products;
- viii. Sharing of regulatory experiences and exchange of information on regulatory requirements for medicines, medical products, active pharmaceutical ingredients of each country, as a first step in order to identify the possibility of developing joint fields of work;
- ix. Laying down modalities for exchange of regulatory and public health information for routine and/or emergency purposes.

BRICS countries have broadly accorded consensus on the above mentioned areas of co-operation.