

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

**RAJYA SABHA
STARRED QUESTION NO. 155
TO BE ANSWERED ON THE 10TH DECEMBER, 2024**

**MEASURES TO SAFEGUARD GENETIC INFORMATION OF INDIAN
NATIONALS**

155 SMT. JEBI MATHER HISHAM:

Will the Minister of Health and Family Welfare be pleased to state:

- (a) the measures taken to ensure that the genetic information of Indian nationals doesn't get leaked or handed over abroad, the details thereof;
- (b) whether Government has recognised the need to bring a biosecurity law to safeguard human genetic information;
- (c) whether Government has recognised the need for legislation targeting to limit the easy access of genetic data of Indian nationals by foreign research institutes and Governments, the details thereof; and
- (d) the steps taken to ensure that the unique Ayushman Bharat Health account will not get leaked, sold or handed over without the knowledge or consent of the patients?

**ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)**

(a) to (d) A Statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA
STARRED QUESTION NO. 155 * FOR 10TH DECEMBER, 2024**

(a) to (c)

1) Research:

Research projects undertaken by Indian researchers in collaboration with foreign investigators or with foreign funding agencies, which involve transfer of biological materials as part of the research require necessary government clearances. Currently, following three Committees grant clearances to research proposals involving foreign assistance/collaboration:

- i) Health Ministry's Screening Committee (HMSC) of Department of Health Research (DHR) (for projects from DHR and Non-Governmental institutes)
- ii) Screening Committee for Research Proposals (SCRPP) of Department of Health and Family Welfare (DoHFW) (for Government and Government aided institutes)
- iii) Department of Biotechnology (DBT) Screening Committee.

Generally, a large number of (i) biological samples from which genetic data can be obtained, and (ii) raw genetic data from samples analysed in India, are no longer allowed to be transferred to foreign countries.

2) Commercial purposes:

Directorate General of Foreign Trade (DGFT) on 11th March, 2024 notified an amendment in the export policy of human biological samples under chapter 30 of ITC HS schedule-2. As per this amendment, the export of item that contains Human biological materials/samples/products related to activities governed by the Drugs & Cosmetics Act, 1940 can be exported only after a No Objection Certificate (NOC) is obtained from the Central Drugs Standard Control Organization (CDSCO).

Also, human biological materials not related to activities governed by the Drugs & Cosmetics Act, 1940 can only be exported subject to NOC from Department of Health Research (DHR)/Indian Council of Medical Research (ICMR). The applications for export are reviewed by a committee consisting of members from MHA, ICMR, DGFT,

DBT, DGHS, DCGI and Department of Revenue. Any biological material from which genetic information can be obtained is approved for export only under exceptional circumstances. ICMR has facilitated the submission of application and grant of NOC through an online portal.

(d) The National Health Authority (NHA) has informed that Ayushman Bharat Health Account (ABHA) is a unique identifier for an individual's health record. After creating an ABHA, an individual can access her/his ABHA only after a secured login. 'Privacy by Design' is one of the key guiding principles of Ayushman Bharat Digital Mission (ABDM). ABDM facilitates secure data exchange between the intended stakeholders on ABDM network after the patient's explicit and informed consent.
