The funds released as Central Assistance by Government to the State Governments and Union Territory Administrations for the Leprosy Eradication Programme during the year 1987-88 have been fully utilised.

75 Reconstructive Survey Units and 13 Leprosy Rehabilitation Promotion Units are providing rehabilitation services to the cured leprosy patients. Ministry of Welfare are providing financial assistance to six major Voluntary Organisations working for the welfare and rehabilitation of leprosy cured persons. During 1987-88, the number of beneficiaries were 699. There is no target fixed for rehabilitating cured leprosy patients under the programme.

Controversy over use of Anti-RHD Vaccine

*296. SHRI HANNAN MOLLAH:
SHRI BASUDEB ACHARIA:

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

(a) whether Government propose to refer the anti-RHD vaccine controversy to an experts committee to know its effect on human body; and

(b) if so, whether arguments put forward by the All India Institute of Medical Sciences and Maharashtra Food and Drug Administration on the subject would also be subjected to scrutiny?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) and (b). The main controversial issues relating to anti-RHD vaccines (anti-D Immunoglobulin) are —

(i) Whether final blood products can be tested for HIV anti-bodies by ELISA and Western Blot tests.

(ii) Whether the human immunodeficiency virus is inactivated in the process of manufacturing anti-D Immunoglobulin.

(iii) Whether anti-D Immunoglobulin (injections), withdrawn from distribution, are likely to cause AIDS if allowed to be administered?

These issues and the appropriate course for action have been considered at the meeting of experts held on 6.3.89 and chaired by Director General of Health Services.

The view point of AIIMS is summarised below:—

(i) ELISA test is highly specific. In a product like anti-D Immunoglobulin where the proteins are present in concentrated amounts, it can sometimes give false results. However, the expensive Western Blot Test is advanced and highly specific. The AIIMS subjected the concerned anti-D Immunoglobulin samples of batch 6/88 of M/s Bharat Serum Vaccine Private Limited, to both ELISA and Western Blot Tests. The results were absolutely and unequivocally positive. This indicated that the vaccine was derived from the blood of donors at least some of whom were infected with AIDS virus and were found 'Sero Positive'. Recall of all unused vials of that particular lot of vaccines was therefore advised.

(ii) The test called EIA was carried out to ascertain whether the vaccine samples contained AIDS virus. The result was negative. The interpretation of this was that although the original blood used for making the vaccines was AIDS virus infected, probably during the processing and purifica-

tion process the AIDS virus got destroyed.

(iii) During 1981-85, many blood products including vaccines prepared in USA and Europe, found positive for HIV anti-bodies, were administered to many patients. A large number of these were administered to many patients in Europe. A large number of them were traced and tested. None of them had shown any features of AIDS infection.

(iv) Though the vaccine was derived from the blood of persons infected with AIDS virus, there is no cause of panic because this vaccine is not likely to transmit AIDS virus infection. In future steps must be taken to ensure stringent quality control so that only clean blood from healthy persons is used for manufacturing blood products.

The Commissioner of Food and Drug Administration, Maharashtra, has drawn attention to the various technical issues raised by M/s Bharat Serum and Vaccines Private Limited. These relate primarily to the suitability or unsuitability of ELISA and Western Blot Tests for testing the final blood products for HIV anti-bodies and the inactivation of AIDS virus, in the process of manufacturing anti-D Immunoglobulin.

The arguments by the All India Institute of Medical Sciences, New Delhi and Maharashtra Food and Drug Administration, have to be considered in the light of the following:

(i) It is understood that the ethamol fractionation process for manufacturing anti-D Immunoguloblin inactivates the AIDS virus. However, this process is not followed by M/s Bharat Serum and Vaccine Private Limited.

(ii) If EIA test for antigen gave a positive result, one can positively conclude that the product has AIDS virus. However, the reverse is not true because a very low quantity of the virus in the products as a result of dilution may sometime remain undetected through testing.

(iii) In USA and Europe, testing of blood used for manufacturing of blood products, has been of high order. In case of M/s Bharat Serum and Vaccine Pvt. Ltd. and some other local manufacturers, attempts were made to locate and retest the blood donors whose blood was used for manufacturing anti-D Immunoglobulin. The blood of many such donors has been found to be positive for HIV anti-bodies.

Considering the various aspects of the matter, the Experts meeting on 6-3-89 came to the conclusion that, as a matter of abundant caution and considering that each bleeding was not specifically tested for HIV anti-bodies and many donors are found sero-positive now, the products, which have been withheld from distribution, should be destroyed.

Survey of Teak Growing Areas

*297. SHRI N. TOMBI SINGH: Will the Minister of ENVIRONMENT AND FORESTS be pleased to state:

(a) whether Government have made a comprehensive survey of the teak growing areas in the North Eastern region, particularly on the Manipur Burma border;

(b) if so, the details thereof?

(c) whether any time-bound programme is proposed to be formulated to protect and nurture the teakwood trees in the Manipur Burma border areas; and