

- (iv) Malathion- dusting for insect control is done;
- (v) CMP oil is distributed to people for personal protection;
- (vi) KFD vaccination is given to high risk population;
- (vii) Interstate coordination meeting was conducted in Sindhudurg district;
- (viii) Public Health, Animal Husbandry and Forest Department are working hand in hand for KFD control;
- (ix) Health education of masses utilizing different media is regularly conducted.

#### **Regulatory system for approval of medicines**

749. DR. K.V.P. RAMACHANDRA RAO: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the attention of Government is drawn to the newspaper reports that Government has approved certain medicines to be marketed in India without the justifiable clinical data and scientific evidence;
- (b) if so, the details thereof;
- (c) whether there is any mechanism in Government to check this type of irrational approvals even when such incidents are brought to its notice; and
- (d) whether Government has received any such complaints during the last three years against certain drugs being marketed in India?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) to (c) Some cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) falling under the purview of Rule 122E of the Drugs and Cosmetics Rules, 1945 by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

Apart from issuing repeated statutory directions under Section 33P of the Drugs and Cosmetics Act, 1940 to the State Governments in this regard, the Central Government constituted an Expert Committee under the chairmanship of Prof C.K. Kokate to examine the safety and efficacy of such FDCs.

Based on the recommendations of the Prof. C. K. Kokate Expert Committee, the Central Government prohibited 344 FDCs *vide* notification dated 10.03.2016. Further the Central Government also prohibited 5 FDCs *vide* notification dated 08.06.2017.

However, with respect to the said 344 FDCs, several writ petitions were filed in different High Courts across the country challenging the ban of the FDCs. After that, the High Court of Delhi *vide* its order dated 01.12.2016 quashed the said notification. The Union of India challenged the said order of Delhi High Court before the Supreme Court by way of filing Special Leave Petitions (SLPs). Further, about 20 cases against 5 FDCs prohibited on 08.06.2017 which were pending before various High Courts across the country, were also transferred to Supreme Court. Hon'ble Supreme Court *vide* its order dated 15.12.2017 directed that an analysis be made in greater depth and these cases of (344+5) FDCs should go to the Drugs Technical Advisory Board (DTAB) and/or a Sub-Committee formed by the DTAB for the purpose of having a relook into these cases.

(d) Yes. Some complaints of grant of manufacturing licenses of new drugs by SLAs without due approval of DCG (I) have been received during the period.

#### **Problem of quacks**

750. SHRI ANUBHAV MOHANTY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it has been reported that a quack has used one needle and syringe to inject many patients infecting them with HIV positive;

(b) whether Government is aware of the fact that such quacks are in abundance in the rural and remote areas due to nonavailability of any kind of medical facility available in those areas; and

(c) the steps Government intends to take to bring such quacks to book and provide basic medical facilities in such areas so that the local population doesn't have to depend on such quacks?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) Taking cognizance of the reports in the media alleging that a quack had re-used injection needles to spread HIV infection in Unnao, Uttar Pradesh, the Ministry deputed a team of experts for fact finding. As per fact finding group, it is well established through scientific research that the rate of transmission from infected needle/syringe is 0.3% for HIV. During the visit, the group