who do not respond adequately to treatment (*e.g.* reduction in glycosylated haemoglobin, HbA1c).

(iii) Before starting pioglitazone, the following known risk factors for development of bladder cancer should be assessed in individuals: age; current or past history of smoking; exposure to some occupational or chemotherapy agents such as cyclophosphamide; or previous irradiation of the pelvic region.

(iv) Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age. Elderly patients should start on the lowest possible dose and be regularly monitored because of the risks of bladder cancer and heart failure associated with pioglitazone."

(v) The Central Government has banned 344 Fixed Dose Combinations on 10.03.2016, as these combinations lacked therapeutic rationality/justification.

Prosecutions under Drugs and Magic Remedies Act, 1958

303. SHRI AVINASH PANDE: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the total number of cases registered and prosecuted under Section 3, 4, 5 and 6 of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1958 for the last three years;

(b) the State-wise and year-wise break up thereof;

(c) the number of such cases that resulted in convictions and the awarding of a penalty under Section 7 or Section 8 of the Act; and

(d) the State-wise and year-wise break up thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA): (a) to (d) The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 is administered by the State Governments. As such, the data regarding the cases registered, prosecuted, and those which resulted in convictions and awarding of penalties under various provisions of the Act is not maintained Centrally.

Banning of FDC drugs

304. SHRI SALIM ANSARI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Government has banned more than 300 Fixed Dose Combinations (FDCs) without giving sufficient time to drug makers to present their side;

(b) if so, the details thereof and reasons therefor;

(c) whether all of these banned combinations had the approvals of State Regulatory Authorities; and;

(d) if so, the reasons for banning these approved drugs by Central Government causing huge financial loss to the companies?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA): (a) to (d) Fixed Dose Combinations (FDCs) containing drugs combined together for the first time are treated as 'New Drugs'. These, therefore, require permission from the Drugs Controller General (India) [DCG(I)] before these could be licensed by the State Licensing Authorities (SLAs) for manufacture for sale in the country. Many SLAs had, despite not having the authority to grant licences for new FDCs, continued to grant licences without approval of the DCG(I). In order to address this issue, the Ministry of Health and Family Welfare issued statutory directions to the State Governments to instruct their respective drugs licensing authorities to refrain from granting such licenses. However, the practice was still not discontinued by some of the SLAs.

The Department Related Parliamentary Standing Committee (PSC) on Health and Family Welfare had, in its 59th Report, observed that some State Licensing Authorities had issued manufacturing licences for a very large number of FDCs without prior clearance from CDSCO and this had resulted in the availability of many FDCs in the market which have not been tested for efficacy and safety. The Committee had also noted that this could put patients at risk.

The Parliamentary Standing Committee had also expressed the view that those unauthorized FDCs that pose risk to patients and communities, such as a combination of two antibacterials, need to be withdrawn immediately due to the danger of developing resistance that would affect the entire population. DCG(I) had requested all State/UT Drug Controllers to ask the concerned manufacturers in their States to prove the safety and efficacy of such FDCs as had been licensed by SLAs prior to 01.10.2012 without obtaining the approval of DCG(I) within a period of 18 months, failing which, such FDCs would be considered for being prohibited for manufacture and marketing in the country. In reply, CDSCO received approximately 6320 applications from manufacturers for proving the safety and efficacy of these FDCs. On scrutiny, it was observed that many FDCs are being manufactured by a number of applicants. With the approval of the Ministry, CDSCO constituted 10 Expert Committees on 03.02.2014 for examining the safety and efficacy of these FDCs. These Committees could, however, examine only about 295 applications. Subsequent to that the Central Government appointed an Expert Committee to examine the

matter. The Committee was also assisted by eminent experts in different therapeutic areas from premier Medical Institutions and hospitals. The Expert Committee, after detailed examination and deliberations recommended that some of these FDCs lacked therapeutic justification; were found to be pharmacokinetically or pharmacodynamically incompatible; had abuse potential; or could lead to antibiotic resistance in the population. The Expert Committee carried out a comprehensive review of the FDCs keeping in view the contemporary Scientific knowledge and expertise. On the basis of the recommendations of the Expert Committee, the Government examined the matter further and requested the Committee to provide specific reasons in respect of each FDC that was found to be irrational. The Committee, accordingly reviewed the matter further and finalized its recommendations. After careful consideration of the matter, the Government issued show cause notices to all the manufacturers whose products were found to be irrational and who had submitted their applications to the Central Drugs Standard Control Organization. At the request of the manufacturers, additional time of three months was given to them to respond to the show cause notices. Thereafter, after due consideration of the report and replies, the Government *vide* Gazette Notifications S.O. Nos.705(E) to 1048(E) dated 10.03.2016 prohibited the manufacture for sale, sale and distribution for human use of 344 FDCs with immediate effect in public interest as use of such FDCs was likely to involve risk to human beings whereas safer alternatives to these drugs were available. The FDCs that have been held irrational had been licensed by the State Licensing Authorities without approval of the DCG(I). However, in case of a few of these FDCs, approval had also been given by the DCG(I).

Programmes to check child mortality rates

305. SHRI P. L. PUNIA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the latest data on infant mortality rate in the country, category-wise, *e.g.* Rural and Urban, SC, ST and Others, for each State;

(b) the latest data on neonatal mortality rate in the country, category-wise, *e.g.* Rural and Urban, SC, ST and Others, for each State;

(c) the latest data on under five mortality rate in the country, categorywise, *e.g.* Rural and Urban, SC, ST and Others, for each State; and

(d) the schemes/programmes/funds launched/released to check high child mortality rate during the last three years and the current year, scheme and State/UT-wise?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA): (a) As per Registrar General of India, Sample Registration