1	2	3	4	5	6	7	8	9	10
33.	Dadra and Nagar Haveli	641	1	1154	0	4161	2	258	0
34.	Daman and Diu	46	0	165	0	89	0	2	0
35.	Puducherry	1322	1	771	0	490	2	273	0
	TOTAL	40571	137	99913	220	129166	245	20664	22

Regulation of FDCs

304. PROF. M. V. RAJEEV GOWDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government intends on regulating fixed-dose combinations (FDCs) so as to eliminate those without rational therapeutic justification, if so, the details thereof, if not, the reasons therefor;

(b) whether Government intends on necessitating bio-equivalence studies for those generic drugs approved before 3 April, 2017, if so, the details thereof, if not, the reasons therefor; and

(c) whether Government intends on integrating all drug regulators into one database to enable access to information regarding substandard drugs to all citizens, if so, the details thereof, if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI FAGGAN SINGH KULASTE): (a) 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), appointed by the respective State Governments, 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unauthorized FDCs that pose risk to patients and communities, such as a combination of two antibacterials, need to be withdrawn immediately due to the danger of developing resistance that would affect the entire population.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 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. These notifications were issued after a detailed scientific assessment and examination of all pertinent issues. However many manufacturers filed a number of cases in different high courts. The Hon'ble High

Court of Delhi has quashed these notifications *vide* its judgment dated 01.12.2016 and the Government has filed appeal before the Hon'ble Supreme Court of India.

Further, in pursuance of the action taken note on the 59th PSC report, based on the examination by the Subject Expert Committee constituted by the Central Government, the Government *vide* Gazette Notifications S.O. Nos.1851(E) to 1855 (E) dated 08.06.2017 prohibited the manufacture for sale, sale and distribution for human use five FDCs with immediate effect in public interest.

(b) Drugs and Cosmetics Rules, 1945 were amended *vide* GSR No.327 (E) dated 03.04.2017, wherein, there is a requirement that "the applicant shall submit the result of bioequivalence study referred to in Schedule Y, along with the application for grant of a license of oral dosage form of drugs specified under category II and category IV of the biopharmaceutical classification system".

(c) Central Drugs Standard Control Organisation (CDSCO), as part of its comprehensive e-Governance program, has launched an online portal "SUGAM". Modules for creation of databases of drug manufacturing facilities, approved drug formulations and retail and wholesale licenses issued in the country have been developed under the portal SUGAM. With regard to the database of the drug manufacturing facilities and approved drug formulations, the data is uploaded by the respective manufacturers and subsequently authenticated by the concerned State Drugs Controllers.

National Policy on Thalassemia

305. PROF. M. V. RAJEEV GOWDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government intends on bringing out a National Policy on Thalassemia in order to create awareness and to prevent its further spread, if so, the details thereof, if not, the reasons therefor;

(b) whether Government intends on making carrier testing compulsory for relatives of Thalassemia patients, if so, the details thereof, if not, the reasons therefor; and

(c) what are the steps being implemented currently by Government to further research on Thalassemia gene therapy in India?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI ANUPRIYA PATEL): (a) and (b) Public Health is a State subject. However, the Ministry has prepared and issued comprehensive guideline for Haemoglobinopathies (Thalassemia, Sickle cell anemia and other variant anemia) for prevention and management of Haemoglobinopathies.