

# An Updated Review on Banned and Approved Fixed Dose Combination Drugs in India, 2016

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## ABSTRACT

The Indian pharma industry ranks 14<sup>th</sup> in terms of value and 3<sup>rd</sup> in terms of volume in the world. There are 74 US FDA-approved manufacturing facilities in India. A dose is the quantity to be administered at one time, or the total quantity administered during a specified period. A combination of two or more actives in a fixed ratio of doses is known as fixed dose combination. The development of fixed-dose combinations (FDCs) is becoming increasingly important from a public health perspective. However, because of un-avoided dangerous adverse effects, Central Government of India banned about 344 FDCs on March 10<sup>th</sup> 2016 as per recommendations of six-member committee headed by CK Kokate. Banned drugs are still available in India due to lack of awareness and law enforcement. The present article provides a complete list of approved and banned FDCs in 2016. The pharmacist should play an active role in patient education of such banned and approved drugs regularly and then play a key role in maintain healthy India.

**Keywords:** Dose, FDC, Banned drugs, Approved drugs.

## INTRODUCTION

A dose is the quantity to be administered at one time, or the total quantity administered during a specified period. Dosage implies a regimen; it is the regulated administration of individual doses and is usually expressed as a quantity per unit of time<sup>1</sup>. A medication or medicine is a drug taken to cure or ameliorate any symptoms of an illness or medical condition. The use may also be as preventive medicine that has future benefits but does not treat any existing or pre-existing diseases or symptoms. Dispensing of medication is often regulated by governments into three categories—over-the-counter medications, which are available in pharmacies and supermarkets without special restrictions; behind-the-counter medicines, which are dispensed by a pharmacist without needing a doctor's prescription, and prescription only medicines, which must be prescribed by a licensed medical professional, usually a physician<sup>2</sup>.

### Pharmaceutical industry in India

The Indian pharma industry ranks 14<sup>th</sup> in terms of value and 3<sup>rd</sup> in terms of volume in the world. The domestic market was worth US\$13.8 billion in 2013 as per

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers<sup>3</sup>.

In terms of the global market, India currently holds a modest 1–2% share, but it has been growing at approximately 10% per year. India gained its foothold on the global scene with its innovatively engineered generic drugs and active pharmaceutical ingredients, and it is now seeking to become a major player in outsourced clinical research as well as contract manufacturing and research. There are 74 US FDA-approved manufacturing facilities in India, more than in any other country outside the U.S, and in 2005, almost 20% of all Abbreviated New Drug Applications (ANDA) to the FDA are expected to be filed by Indian companies. Growth in other fields notwithstanding, generics is still a large part of the picture<sup>4</sup>.

### Fixed dose combinations (FDCs)

A combination of two or more actives in a fixed ratio of doses is known as fixed dose combination. It may be administered as single entity products given concurrently or as finished pharmaceutical product. The development of fixed-dose combinations (FDCs) is becoming increasingly important from a public health perspective. Such combinations of drugs are being used in the treatment of a wide range of conditions and

are particularly useful in the management of HIV/AIDS, malaria and tuberculosis, which are considered to be the foremost infectious disease threats in the world today. FDCs have advantages when there is an identifiable patient population for whom treatment with a particular combination of actives in a fixed ratio of doses has been shown to be safe and effective and when all of the actives contribute to the overall therapeutic effect. In addition there can be real clinical benefits in the form of increased efficacy and/or a reduced incidence of adverse effects, but such claims should be supported by evidence. Additional advantages of FDCs are potentially lower costs of manufacturing compared to the costs of producing separate products administered concurrently, simpler logistics of distribution, improved patient adherence and reduced development of resistance in the case of antimicrobials. Importantly, as for any new medicine the risks and benefits should be defined and compared<sup>5, 6</sup>.

#### **Banned and Approved Fixed dose combination drugs**

An adverse drug reaction (ADR) as defined by World Health Organization (WHO) is a noxious, unintended effect of a drug, occurring

at normal doses in humans for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function<sup>7</sup>. The fixed dose combinations are banned due to they could artificially improve their performance and shows various adverse effects more than therapeutic effects. Whose production or use is prohibited or strictly controlled via prescription. Banned drugs are still available in India due to lack of awareness and law enforcement. The government of India needs to enforce laws and provide information to public and physicians about banned drugs, approved drugs and the reasons through drug information centers. The pharmacist should play an active role in patient education of drugs regularly and then play an important role on eliminating the market for banned drugs. On the basis of the recommendations of the Expert Committee appointed by the Central Government of India and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government of India prohibits/banned a total of 336 drug fixed dose combinations for the manufacturing, sale and distribution for human use with effect from 10th March, 2016.

**List banned fixed dose combination drugs in 2016<sup>8</sup>**

S. No.	Statutory Orders (S.O.)	Banned fixed dose combination
1	S.O.705(E)	Aceclofenac + Paracetamol + Rabeprazole
2	S.O.706(E)	Nimesulide + Diclofenac
3	S.O.707(E)	Nimesulide + Cetrizine + Caffeine
4	S.O.708(E)	Nimesulide + Tizanidine
5	S.O.709(E)	Paracetamol + Cetrizine + Caffeine
6	S.O.710(E)	Diclofenac + Tramadol + Chlorzoxazone
7	S.O.711(E)	Dicyclomine + Paracetamol + Domperidone
8	S.O.712(E)	Nimesulide + Paracetamol dispersible tablets
9	S.O.713(E)	Paracetamol + Phenylephrine + caffeine
10	S.O.714(E)	Diclofenac + Tramadol + Paracetamol
11	S.O.715(E)	Diclofenac + Paracetamol + Chlorzoxazone + Famotidine
12	S.O.716(E)	Naproxen + Paracetamol
13	S.O.717(E)	Nimesulide + Serratiopeptidase
14	S.O.718(E)	Paracetamol + Diclofenac + Famotidine
15	S.O.719(E)	Nimesulide + Pitofenone + Fenpiverinium + Benzyl alcohol
16	S.O.720(E)	Omeprazole + Paracetamol + Diclofenac
17	S.O.721(E)	Nimesulide+paracetamol injection
18	S.O.722(E)	Tamsulosin + Diclofenac
19	S.O.723(E)	Paracetamol + Phenylephrine + Chlorpheniramine + Dextromethorphan + Caffeine
20	S.O.724(E)	Diclofenac + Zinc carnosine
21	S.O.725(E)	Diclofenac + Paracetamol + Chlorpheniramine maleate + Magnesium tri silicate
22	S.O.726(E)	Paracetamol + Pseudo ephedrine + Cetrizine
23	S.O.727(E)	Phenyl butazone + Sodium salicylate
24	S.O.728(E)	Lornoxicam + Paracetamol + Trypsin
25	S.O.729(E)	Paracetamol + Mefenamic acid + Ranitidine + Dicyclomine
26	S.O.730(E)	Nimesulide + Dicyclomine
27	S.O.731(E)	Heparin + Diclofenac
28	S.O.732(E)	Glucosamine + Methyl sulfonyl methane + Vitamin D <sub>3</sub> + Manganese + Boron + Copper + Zinc
29	S.O.733(E)	Paracetamol + Tapentadol
30	S.O.734(E)	Tranexamic acid + Proanthocyanidin
31	S.O.735(E)	Benzoxonium chloride + Lidocaine
32	S.O.736(E)	Lornoxicam + Paracetamol + Tramadol

33	S.O.737(E)	Lornoxicam + Paracetamol + Serratiopeptidase
34	S.O.738(E)	Diclofenac + Paracetamol + Magnesium trisilicate
35	S.O.739(E)	Paracetamol + Domperidone + Caffeine
36	S.O.740(E)	Ammonium chloride + Sodium citrate + Chlorpheniramine maleate + Menthol
37	S.O.741(E)	Paracetamol + Prochlorperazine maleate
38	S.O.742(E)	Serratiopeptidase (Enteric coated 20000 units) + Diclofenac potassium & 2 Tablets of Doxycycline
39	S.O.743(E)	Nimesulide + Paracetamol suspension
40	S.O.744(E)	Aceclofenac + paracetamol + Famotidine
41	S.O.745(E)	Aceclofenac + Zinc carnosine
42	S.O.746(E)	Paracetamol + disodium hydrogen citrate + Caffeine
43	S.O.747(E)	Paracetamol + DL Methionine
44	S.O.748(E)	Disodium hydrogen citrate + Paracetamol
45	S.O.749(E)	Paracetamol + Caffeine + Codeine
46	S.O.750(E)	Aceclofenac (SR) + Paracetamol
47	S.O.751(E)	Diclofenac+Paracetamol injection
48	S.O.752(E)	Azithromycin+Cefixime
49	S.O.753(E)	Amoxicillin+Dicloxacillin
50	S.O.754(E)	Amoxicillin 250mg+Potassium Clavulanate Diluted 625mg
51	S.O.755(E)	Azithromycin+Levofloxacin
52	S.O.756(E)	Cefixime+Linezolid
53	S.O.757(E)	Amoxicillin+Cefixime+Potassium clavulanic acid
54	S.O.758(E)	Ofloxacin +Nitazoxanide
55	S.O.759(E)	CefpodoximeProxetil+ Levofloxacin
56	S.O.760(E)	Azithromycin+Secnidazole+Fluconazole
57	S.O.761(E)	Levofloxacin+Ornidazole+Alpha Tocopherol Acetate
58	S.O.762(E)	Nimorazole+ofloxacin
59	S.O.763(E)	Azithromycin +Ofloxacin
60	S.O.764(E)	Amoxcillin+Tinidazole
61	S.O.765(E)	Doxycycline+Serratiopeptidase
62	S.O.766(E)	Cefixime+Levofloxacin
63	S.O.767(E)	Ofloxacin+Metronidazole+Zinc acetate
64	S.O.768(E)	Diphenoxylate +Atropine+Furazolidone
65	S.O.769(E)	Flucanazoletablet+Azithromycintablet+Ornidazole tablet
66	S.O.770(E)	Ciprofloxacin+phenazopyridine
67	S.O.771(E)	Amoxycillin+Dicloxacillin+Serratiopeptidase
68	S.O.772(E)	Azithromycin+Cefpodoxime
69	S.O.773(E)	Lignocaine+clotrimoxazole+Ofloxacin+Beclomethasone
70	S.O.774(E)	Cefuroxime+Linezolid
71	S.O.775(E)	Ofloxacin+Ornidazole+ZincBisglycinate
72	S.O.776(E)	Metronidazole+Norfloxacin
73	S.O.777(E)	Amoxicillin+Bromhexine
74	S.O.778(E)	Ciprofloxacin+Fluticasone+Clotrimoxazole+Neomycin
75	S.O.779(E)	Metronidazole+Tetracyclin
76	S.O.780(E)	Cephalexin+Neomycin+Prednisolone
77	S.O.781(E)	Azithromycin+Ambroxol
78	S.O.782(E)	Cilnidipine+Metoprololsuccinate+MetoprololTartarate
79	S.O.783(E)	L-Arginine+Sildenafil
80	S.O.784(E)	Atorvastatin+Vitamin D <sub>3</sub> +Folic acid +Vitamin B <sub>12</sub> +Pyridoxine
81	S.O.785(E)	Metformin+Atorvastatin
82	S.O.786(E)	Clindamycin +Telmisartan
83	S.O.787(E)	Olmesartan+Hydrochlorothiazide+Chlorthalidone
84	S.O.788(E)	L-5Methyltetrahydrofolate calcium+Escitalopram
85	S.O.789(E)	Pholcodine+Promethazine
86	S.O.790(E)	Paracetamol+Promethazine
87	S.O.791(E)	Betahistine+GinkgoBiloba Extract+ Vinpocetine +Piracetam
88	S.O.792(E)	Cetirizine+Diethyl Carbamazine
89	S.O.793(E)	Doxylamine+Pyridoxine+Mefenamicacid+Paracetamol
90	S.O.794(E)	Drotaverine+Clidinium+Chlordiazepoxide
91	S.O.795(E)	Imipramine+Diazepam
92	S.O.796(E)	Flupentixol+Escitalopram
93	S.O.797(E)	Paracetamol+Prochlorperazine
94	S.O.798(E)	Gabapentin+Mecobalamin+Pyridoxine+Thiamine
95	S.O.799(E)	Imipramine+Chlordiazepoxide+Trifluoperazine+Trihexyphenidyl
96	S.O.800(E)	Chlorpromazine+Trihexylphenidyl
97	S.O.801(E)	Ursodeoxycholic Acid + Silymarin
98	S.O.802(E)	Metformin 1000/1000/500/500mg+Pioglitazone 7.5/7.5/7.5/7.5 mg+Glimepiride
99	S.O.803(E)	Gliclazide 80mg+Metformin 325 mg
100	S.O.804(E)	Voglibose+Metformin+ChromiumPicolinate
101	S.O.805(E)	Pioglitazone 7.5/7.5 mg+Metformin 500/1000 mg
102	S.O.806(E)	Glimepiride 1mg/2mg/3mg+Pioglitazone 15mg/15 mg/15mg+Metformin 1000mg/1000mg/1000mg
103	S.O.807(E)	Glimepiride 1mg/2mg+Pioglitazone 15mg/15mg+Metformin 850mg/850mg

104	S.O.808(E)	Metformin 850mg+ Pioglitazone 7.5mg+Glimepride 2mg
105	S.O.809(E)	Metformin 850mg+pioglitazone 7.5mg+Glimepride 1mg
106	S.O.810(E)	Metformin 500mg/500mg+Gliclazide SR 30mg/60mg+Pioglitazone 7.5mg/7.5mg
107	S.O.811(E)	Voglibose +Pioglitazone+Metformin
108	S.O.812(E)	Metformin+Bromocriptine
109	S.O.813(E)	Metformin+Glimepride+Methylcobalamin
110	S.O.814(E)	Pioglitazone 30 mg+ Metformin 500mg
111	S.O.815(E)	Glimepride+Pioglitazone+Metformin
112	S.O.816(E)	Glipizide 2.5 mg+Metformin 400 mg
113	S.O.817(E)	Pioglitazone 15mg+Metformin 850 mg
114	S.O.818(E)	Metformin ER+ Gliclazide MR+ Voglibose
115	S.O.819(E)	Chromium polynicotinate+Metformin
116	S.O.820(E)	Metformin+Gliclazide+Pioglitazone+Chromiumpolynicotinate
117	S.O.821(E)	Metformin+Gliclazide+ChromiumPolynicotinate
118	S.O.822(E)	Glibenclamide+Metformin (SR) +Pioglitazone
119	S.O.823(E)	Metformin SR 500mg+Pioglitazone 15mg+ Glimepride 3 mg
120	S.O.824(E)	Metformin SR 500mg+Pioglitazone 5mg
121	S.O.825(E)	Chloramphenicol +Betamethasone+Clotrimoxazole+Lignocaine
122	S.O.826(E)	Clotrimazole +Ofloxacin+Lignocaine+Glycerine+Propylene Glycol
123	S.O.827(E)	Chloramphenicol+Lignocaine+Betamethasone+Clotrimazole+Ofloxacin+Antipyrine
124	S.O.828(E)	Ofloxacin+Clotrimazole+Betamethasone+Lignocaine
125	S.O.829(E)	Gentamicin sulphate +Clotrimazole+Betamethasone+Lignocaine
126	S.O.830(E)	Clotrimazole+Beclomethasone+Ofloxacin+Lignocaine
127	S.O.831(E)	Beclomethasone+Clotrimazole+Chloramphenicol+Gentamicin+Lignocaine
128	S.O.832(E)	Flunarizine+Paracetamol+Domperidone
129	S.O.833(E)	Rabeprazole+ZincCarnosine
130	S.O.834(E)	Magaldrate+Famotidine+Simethicone
131	S.O.835(E)	Cyproheptadine+Thiamine
132	S.O.836(E)	Magaldrate+Ranitidine+Pancreatin+Domperidone
133	S.O.837(E)	Ranitidine+Magaldrate+Simethicone
134	S.O.838(E)	Maglrate+Papain+FungalDiastase+Simethicone
135	S.O.839(E)	Rabeprazole+Zinc+Domperidone
136	S.O.840(E)	Famotidine+Oxytaccine+Magaldrate
137	S.O.841(E)	Ranitidine+Domperidone+Simethicone
138	S.O.842(E)	Alginic acid+SodiumBicarbonate+Dried Aluminium Hydroxide+ Magnesium Hydroxide
139	S.O.843(E)	Clidinium+Paracetamol+Dicyclomine+ActivatedDimethicone
140	S.O.844(E)	Furazolidone+Metronidazole+Loperamide
141	S.O.845(E)	Rabeprazole+Diclofenac+Paracetamol
142	S.O.846(E)	Ranitidine+Magaldrate
143	S.O.847(E)	Norfloxacin+Metronidazole+Zinc acetate
144	S.O.848(E)	Zinc Carnosine+Oxetacaine
145	S.O.849(E)	Oxetacaine+Magaldrate+Famotidine
146	S.O.850(E)	Pantoprazole(as enteric Coated Tablet) +Zinc Carnosine
147	S.O.851(E)	Zinc Carnosine+Magnesium Hydroxide+Dried Aluminium Hydroxide+Simethicone
148	S.O.852(E)	Zinc Carnosine+ Sucralfate
149	S.O.853(E)	Mebeverine&Inner HPMC capsule
150	S.O.854(E)	Clindamycin+Clotrimazole+Lactic acid bacillus
151	S.O.855(E)	Sildenafil+EstradiolValerate
152	S.O.856(E)	ClomifeneCitrate+Ubidecarenone+Zinc+Folicacid+Methylcobolamin+Pyridoxine+Lycopene+Selenium+LevocarnitineTartarate+L-Arginine
153	S.O.857(E)	Thyroxine +Pyridoxine+Folic acid
154	S.O.858(E)	Gentamicin+Dexamethasone+Chloramphenicol+Tobramycin+Ofloxacin
155	S.O.859(E)	Dextromethorphan+Levocetirizine+Phenylephrine+Zinc
156	S.O.860(E)	Nimesulide+Loratadine+Phenylephrine+Ambroxol
157	S.O.861(E)	Bromohexine+Phenylephrine+Chlorepheniramine Maleate
158	S.O.862(E)	Dextromethorphan+Bromohexine+Guaiphenesin
159	S.O.863(E)	Paracetamol+Loratadine+Phenylephrine+Dextromethorphan+Caffeine
160	S.O.864(E)	Nimesulide+Phenylephrine+Caffeine+Levocetirizine
161	S.O.865(E)	Azithromycin+Acebrophylline
162	S.O.866(E)	Diphenhydramine+Terpine+AmmoniumChloride+SodiumChloride+Menthol
163	S.O.867(E)	Nimesulide+Paracetamol+Cetirizine+Phenylephrine
164	S.O.868(E)	Paracetamol+Loratadine+Dextromethorphan+Pseudoephdrine+Caffeine
165	S.O.869(E)	ChlorpheniramineMaleate+Dextromethorphan+Dextromethophan+Guaiphenesin+Ammoniumchloride+Menthol
166	S.O.870(E)	Chlorpheniramine Maleate+ Ammonium chloride+Sodium citrate
167	S.O.871(E)	Cetirizine+Phenylephrine+Paracetamol+Zinc Gluconate
168	S.O.872(E)	Ambroxol+Guaiphenesin+Ammonium Chloride+Phenylephrine+Chlorpheniramine Maleate+ Menthol
169	S.O.873(E)	Dextromethorphan+Bromohexine+ChlorpheniramineMaleate+Guaiphenesin
170	S.O.874(E)	Levocetirizine+Ambroxol+Phenylephrine+Guaiphenesin
171	S.O.875(E)	Dextromethorphan+Chlorpheniramine+ Chlorpheniramine Maleate
172	S.O.876(E)	Cetirizine+Ambroxol+Guaiphenesin+AmmoniumChloride+Phenylephrine+Menthol
173	S.O.877(E)	Chlorpheniramine+Phenylephrine+Caffeine

174	S.O.878(E)	Dextromethorphan+Triprolidine+Phenylephrine
175	S.O.879(E)	Terpinhydrate+Dextromethorphan+Menthol
176	S.O.880(E)	Dextromethorphan+Phenylephrine+Zinc Gluconate+Menthol
177	S.O.881(E)	Chlorpheniramine+Codiene+Sodium citrate+Menthol Syrup
178	S.O.882(E)	Enrofloxacin+Bromhexin
179	S.O.883(E)	Bromhexine+Dextromethorphan+Phenylephrine+Menthol
180	S.O.884(E)	Levofloxacin+Bromhexine
181	S.O.885(E)	Levocetirizine+Ranitidine
182	S.O.886(E)	Levocetirizine+Phenylephrine+Ambroxol+Guaiphenesin+Paracetamol
183	S.O.887(E)	Cetirizine+Dextromethorphan+Phenylephrine+Zinc Gluconate+Paracetamol+Menthol
184	S.O.888(E)	Paracetamol+Pseudoephedrine+Dextromethorphan+Cetirizine
185	S.O.889(E)	Diphenhydramine+Guaiphenesin+Ammonium Chloride+Bromhexine
186	S.O.890(E)	Chlorpheniramine+Dextromethorphan+Phenylephrine+Pracetamol
187	S.O.891(E)	Dextromethorphan+Promethazine
188	S.O.892(E)	Diethylcabamazine Citrate+Cetirizine+Guaiphenesin
189	S.O.893(E)	Pseudoephedrine+Dextromethorphan+Cetirizine
190	S.O.894(E)	Chlorpheniramine+Phenylephrine+Dextromethophan+Menthol
191	S.O.895(E)	Ambroxol+Terbutaline+Dextromethorphan
192	S.O.896(E)	Dextromethorphan+Chlorpheniramine+Guaiphenesin
193	S.O.897(E)	Terbutaline+ Bromhexine +Guaiphenesin +Dextromethorphan
194	S.O.898(E)	Dextromethorphan+Triprolidine+Phenylephrine
195	S.O.899(E)	Paracetamol+Dextromethorphan+Chlorpheniramine
196	S.O.900(E)	Pholcodine+Phenylephrine+Promethazine
197	S.O.901(E)	Codiene+Levocetirizine+Menthol
198	S.O.902(E)	Dextromethorphan+Ambroxol+Guaiphenesin+Phenylephrine+Chlorpheniramine
199	S.O.903(E)	Cetirizine+Phenylephrine+Dextromethorphan+Menthol
200	S.O.904(E)	Roxithromycin+Serratiopeptidase
201	S.O.905(E)	Paracetamol+Phenylephrine+Triprolidine
202	S.O.906(E)	Acetaminophen+Loratadine+Ambroxol+Phenylephrine
203	S.O.907(E)	Cetirizine+Acetaminophen+Dextromethorphan+Phenylephrine+ZincGluconate
204	S.O.908(E)	Diphenhydramine+Guaiphenesin+Bromhexine+AmmoniumChloride+Menthol
205	S.O.909(E)	Chlorpheniramine Maleate+Codiene Syrup
206	S.O.910(E)	Cetirizine+Dextromethorphan+Zinc Gluconate+Menthol
207	S.O.911(E)	Paracetamol+Phenylephrine+Desloratadine+Zinc Gluconate+Ambroxol
208	S.O.912(E)	Levocetirizine+Montelukast+Acebrophylline
209	S.O.913(E)	Dextromethorphan+Phenylephrine+Ammonium Chloride+Menthol
210	S.O.914(E)	Dextromethorphan+Bromhexine+Guaiphenesin+Menthol
211	S.O.915(E)	Acrivastine+Paracetamol+Caffeine+Phenylephrine
212	S.O.916(E)	Naphazoline+Carboxy Methyl Cellulose+Menthol+Camphor+Phenylephrine
213	S.O.917(E)	Dextromethorphan+Cetirizine
214	S.O.918(E)	Nimesulide+Paracetamol+Levocetirizine+Phenylephrine+Caffeine
215	S.O.919(E)	Terbutaline+Ambroxol+Guaiphenesin+Zinc+Menthol
216	S.O.920(E)	Codeine+Chlopheniramine+Alcohol Syrup
217	S.O.921(E)	Dextromethorphan+Phenylephrine+Guaiphenesin+Triprolidine
218	S.O.922(E)	Ammonium Chloride+Bromhexine+Dextromethorphan
219	S.O.923(E)	Diethylcarbamazine+Cetirizine+Ambroxol
220	S.O.924(E)	Ethylmorphine+Noscapine+Chlorpheniramine
221	S.O.925(E)	Cetirizine+Dextromethorphan+Ambroxol
222	S.O.926(E)	Bromhexine+Dextromethorphan+Ammonium Chloride+Menthol
223	S.O.927(E)	Ambroxol+Guaiphenesin+Phenylephrine+Chlorpheniramine
224	S.O.928(E)	Paracetamol+phenylephrine+Chlorpheniramine+Zinc Gluconate
225	S.O.929(E)	Dextromethorphan+Phenylephrine+Cetirizine+Paracetamol+Caffeine
226	S.O.930(E)	Dextromethorphan+Chlorpheniramine+Guaiphenesin+Ammonium Chloride
227	S.O.931(E)	Levocetirizine+Dextromethorphan+Zinc
228	S.O.932(E)	Paracetamol+phenylephrine+Levocetirizine+Caffeine
229	S.O.933(E)	Chlorpheniramine+Ammonium Chloride+ Sodium Chloride
230	S.O.934(E)	Paracetamol+Dextromethorphan+Bromhexine+Phenylephrine+Diphenhydramine
231	S.O.935(E)	Salbutamol+Bromhexine+Guaiphenesin+Menthol
232	S.O.936(E)	Chlorpheniramine+AmmoniumChloride+Noscapine+Sodium Citrate
233	S.O.937(E)	Cetirizine+Dextromethorphan+Bromhexine+Guaiphenesin
234	S.O.938(E)	Diethyl Carbamazine+Chlorpheniramine+Guaiphenisn
235	S.O.939(E)	Ketotifen+Cetirizine
236	S.O.940(E)	Terbutaline+Bromhexine+Etofyline
237	S.O.941(E)	Ketotifen+Theophylline
238	S.O.942(E)	Ambroxol+Salbutamol+Theophylline
239	S.O.943(E)	Cetirizine+Nimesulide+Phenylephrine
240	S.O.944(E)	Chlorpheniramine+Phenylephrine+Paracetamol+ZincGluconate
241	S.O.945(E)	Acetaminophen+Guaiphenesin+Dextromethorphan+Chlorpheniramine
242	S.O.946(E)	Cetirizine+Dextromethorphan+Phenylephrine+Tulasi
243	S.O.947(E)	Cetirizine+Phenylephrine+Paracetamol+Ambroxol+Caffeine
244	S.O.948(E)	Guaiphenesin+Dextromethorphan



245	S.O.949(E)	Levocetirizine+Paracetamol+Phenylephrine+Caffeine
246	S.O.950(E)	Caffeine+Paracetamol+Phenylephrine+Chlorpheniramine
247	S.O.951(E)	Ketotifen+Levocetirizine
248	S.O.952(E)	Paracetamol+Levocetirizine+Phenylephrine+Zinc Gluconate
249	S.O.953(E)	Paracetamol+Phenylephrine+Triprolidine+Caffeine
250	S.O.954(E)	Caffeine+Paracetamol+Phenylephrine+Cetirizine
251	S.O.955(E)	Dextromethorphan + Phenylephrine + Guaifenesin
252	S.O.956(E)	Ambroxol + Levocetirizine + Phenylephrine + Guaifenesin + Menthol
253	S.O.957(E)	Pseudoephedrine + Cetirizine
254	S.O.958(E)	Dextromethorphan + Chlorpheniramine + Ammonium Chloride + Menthol
255	S.O.959(E)	Paracetamol + Caffeine + Phenylephrine + Chlorpheniramine
256	S.O.960(E)	Salbutamol + Aminophylline + Guaifenesin
257	S.O.961(E)	Salbutamol + Theophylline + Bromhexine
258	S.O.962(E)	Chlorpheniramine + Dextromethorphan + Guaifenesin + Phenylephrine
259	S.O.963(E)	Caffeine + Paracetamol + Chlorpheniramine
260	S.O.964(E)	Ammonium Chloride+Dextromethorphan+Cetirizine+Menthol
261	S.O.965(E)	Dextromethorphan+Paracetamol+Cetirizine+Phenylephrine
262	S.O.966(E)	Chlorpheniramine+Terpin+Antimony Potassium Tartarate+Ammonium Chloride+SodiumCitrate+Menthol
263	S.O.967(E)	Terbutaline+Etofylline+Ambroxol
264	S.O.968(E)	Paracetamol+Codeine+Chlorpheniramine
265	S.O.969(E)	Paracetamol+Pseudoephedrine+Cetirizine+Caffeine
266	S.O.970(E)	Chlorpheniramine+AmmoniumChloride+Menthol
267	S.O.971(E)	N-Acetyl Cysteine+Ambroxol+Phenylephrine+Levocetirizine
268	S.O.972(E)	Dextromethorphan+Phenylephrine+Triprolidine+Menthol
269	S.O.973(E)	Salbutamol+Cetirizine+Ambroxol
270	S.O.974(E)	Dextromethorphan+Phenylephrine+Bromohexine+Guaifenesin+Chlorpheniramine
271	S.O.975(E)	Nimesulide+Cetirizine+Phenylephrine
272	S.O.976(E)	Naphazoline+Chlorpheniramine+ZincSulphate+BoricAcid+SodiumChloride+Chlorobutol
273	S.O.977(E)	Paracetamol+Bromohexine+Phenylephrine+Chlorpheniramine+Guaifenesin
274	S.O.978(E)	Salbutamol+Bromohexine
275	S.O.979(E)	Dextromethorphan+Phenylephrine+Guaifenesin+Cetirizine+Acetaminophen
276	S.O.980(E)	Guaifenesin+Bromohexine+Chlorpheniramine+Paracetamol
277	S.O.981(E)	Chlorpheniramine+AmmoniumChloride+Chlorform+Menthol
278	S.O.982(E)	Salbutamol+CholineTheophylline+Ambroxol
279	S.O.983(E)	Chlorpheniramine+Codeinephosphate+Menthol syrup
280	S.O.984(E)	Pseudoephedrine+Bromohexine
281	S.O.985(E)	Cetirizine+Phenylephrine+Paracetamol+Caaffeine+Nimesulide
282	S.O.986(E)	Dextromethorphan+Cetirizine+Guaifenesine+Ammonium Chloride
283	S.O.987(E)	Ambroxol+Salbutamol+CholineTheophyllinate+Menthol
284	S.O.988(E)	Paracetamol+Chlorpheniramine+Ambroxol+Guaifenesine+Phenylephrine
285	S.O.989(E)	Chlorpheniramine+Vasaka+Tolubalsam+AmmoniumChloride+Sodiumcitrate+Menthol
286	S.O.990(E)	Bromhexine+Cetirizine+PhenylephrineIP+Guaifenesin+Menthol
287	S.O.991(E)	Dextromethorphan+Ambroxol+AmmoniumChloride+Chlorpheniramine+Menthol
288	S.O.992(E)	Dextromethorphan+Phenylephrine+Cetirizine+Zinc+Menthol
289	S.O.993(E)	Terbutaline+N-AcetylL-Cysteine+Guaifenesin
290	S.O.994(E)	Calcium Gluconate+Levocetirizine
291	S.O.995(E)	Paracetamol+Levocetirizine+Pseudoephedrine
292	S.O.996(E)	Salbutamol+CholineTheophyllinate+Carbocisteine
293	S.O.997(E)	Chlorpheniramine+Vitamin C
294	S.O.998(E)	Calcium Gluconate+Chlorpheniramine+Vitamin C
295	S.O.999(E)	Chlorpheniramine+Paracetamol+Pseudoephedrine+Caffeine
296	S.O.1000(E)	Guaifenesine+Bromohexine+Chlorpheniramine+phenylphrine+Paracetamol+Serratiopeptidase
297	S.O.1001E)	Paracetamol+pheniramine
298	S.O.1002E)	Betamethasone+FusidicAcid+Gentamicin+Tolnaftate+Iodochlorhydroxyquinoline
299	S.O.1003E)	Clobetasol+Ofloxacin+Miconazole+Zinc Sulphate
300	S.O.1004E)	Clobetasole+Gentamicin+Miconazole+Zinc Sulphate
301	S.O.1005E)	Levocetirizine+Ambroxol+Phenylephrine+Paracetamol
302	S.O.1006E)	Permethrin+Cetrimide+Menthol
303	S.O.1007E)	Beclomethasone+Clotrimazole+Neomycin+Iodochlorhydroxyquinone
304	S.O.1008E)	Neomycin+Doxycycline
305	S.O.1009(E)	Ciprofloxacin+Fluocinolone+Clotrimazole+Neomycin+Chlorocresol
306	S.O.1010(E)	Clobetasol+Ofloxacin+Ketoconazol+Zinc Sulphate
307	S.O.1011(E)	Betamethasone+Gentamycin+Tolnaftate+Iodochlorhydroxyquinoline
308	S.O.1012(E)	Clobetasol+Gentamycin+Tolnaftate+Iodochlorhydroxyquinone+Ketaconazole
309	S.O.1013(E)	Allantoin+Dimethieone+Urea+Propylene+Glycerin+Liquid paraffin
310	S.O.1014(E)	Acriflavine+Thymol+Cetrimide
311	S.O.1015(E)	Betamethasone+Neomycin+Tolnaftate+Iodochlorhydroxyquinoline+Chlocresol
312	S.O.1016(E)	Clobetasol+Neomycin+Miconazole+Clotrimazole
313	S.O.1017(E)	Ketoconazole+Tea Tree Oil+Allantoin+Zinc Oxide+Aloevera+Jojoba Oil+Lavendar Oil+Soa Noodles
314	S.O.1018(E)	ClobetasolPropionate+Ofloxacin+Ornidazole+Terbinafine
315	S.O.1019(E)	Clobetasol+Neomycin+Miconazole+Zinc Sulphate

316	S.O.1020(E)	Beclomethasone+Dipropionate+Neomycin+Tolnaftate+Iodochlorhydroxyquinoline+Chlorocresol
317	S.O.1021(E)	Betamethasone+Gentamycin+Zinc Sulphate+Clotrimazole+Chlorocresol
318	S.O.1022(E)	Borax+Boricacid+Naphazoline+Menthol+Camphor+MethylHydroxy Benzoate
319	S.O.1023(E)	Bromohexine+Dextromethorphan
320	S.O.1024(E)	Dextromethorphan+Chlorpheniramine+Bromohexine
321	S.O.1025(E)	Menthol+Anesthetic Ether
322	S.O.1026(E)	Dextromethorphan+Chlorpheniramine+Ammonium+Sodiumcitrate+Menthol
323	S.O.1027(E)	Ergotamine Tartarate+Belladonna Dry Extract+Caeffine+Paracetamol
324	S.O.1028(E)	Phenytoin+Phenobarbitone
325	S.O.1029(E)	Gliclazide 40mg+Metformin 400 mg
326	S.O.1030(E)	Paracetamol+Ambroxol+Phenylephrine+Chlorpheniramine
327	S.O.1031(E)	Ofloxacin+Ornidazole Suspension
328	S.O.1032(E)	Albuterol+Etofylline+Bromohexine+Menthol
329	S.O.1033(E)	Albuterol+Bromohexine+Theophylline
330	S.O.1034(E)	Salbutamol+Etofylline+Bromohexine
331	S.O.1035(E)	Paracetamol+Phenylephrine+Levocetirizine+Sodium citrate
332	S.O.1036(E)	Paracetamol+Propyphenazone+Caeffine
333	S.O.1037(E)	Guaiphenesin+Diphenhydramine+Bromhexine+Phenylephrine
334	S.O.1038(E)	Dried Aluminum Hydroxide Gel+Prophantheline+Diazepam
335	S.O.1039(E)	Bromhexine+Phenylephrine+Chlorpheniramine+Paracetamol
336	S.O.1040(E)	Beclomethasone+Clotrimazole+Gentamicin+Iodochlorhydroxyquinoline
337	S.O.1041(E)	Telmisartan+Metformin
338	S.O.1042(E)	Ammonium Citrate Vitamin B <sub>12</sub> +Folic Acid+Zinc Sulphate
339	S.O.1043(E)	Levothyroxine+Phyridoxine+Nicotinamide
340	S.O.1044(E)	Benfotiamine+Metformin
341	S.O.1045(E)	Thyroid+Thiamine+Riboflavin+Pyridoxine+CalciumPantothenate+Tocopherylacetate+Nicotenamide
342	S.O.1046(E)	Ascorbic Acid+Mannadione Sodium Bisulphate+Rutin+Dibasic Calcium Phosphate+Adrenochromemonosemicarbazone
343	S.O.1047(E)	Phenylephrine+Chlorpheniramine+Paracetamol+Bromohexine+Caeffine
344	S.O.1048(E)	Clotrimazole+Beclomethasone+Lignocaine+Ofloxacin+Acetic Acid +Sodium Methyl Paraben+PropylParaben

**List of fixed dose combinations drugs approved by DCG (I) from 01<sup>st</sup> Jan 2016 to till date<sup>9</sup>**

S. No.	Combination	Indication	Date of approval
1	Teneligliptin Hydrobromide Hydrate Eq. to Teneligliptin 20mg +Metformin- 500mg/1000mg (ER) Tablets	For treatment of type 2 diabetes mellitus.	05.01.16
2	Brinzolamide - 1.0% w/v + Timolol maleate – 0.683% w/v Eq. to Timolol 0.5% w/v Ophthalmic suspension	Decrease of intraocular pressure (IOP) in adults patients with open angle glaucoma.	18.02.16
3	Emtricitabine 200mg +Tenofovir DisoproxilFumarate 300mg eq. to Tenofovir Disoproxil 245mg Tablet (additional Indication)	In combination with safer sex practices for pre-exposure. Prophylaxis to reduce the risk of sexually acquired HIV-1 in adults at high risk.	17.02.16
4	Rifampicin - 75mg +Isoniazid -50mg+ Pyrazinamide -150 mg dispersible tablet (additional strength)	For the treatment of tuberculosis in children.	08.03.16
5	Clopidogrel Bisulphate eq. to Clopidogrel 75mg +Aspirin 100mg tablets (additional strength)	For the treatment of angina and myocardial infarction.	15.03.16
6	Rifampicin 75mg+Isoniazid 50mg dispersible tablet (additional strength)	For the treatment of tuberculosis in children.	11.03.16
7	Brinzolamide 10mg,+Brimonidine Tartrate eq. to Brimonidine 2mg Ophthalmic suspension	For the reduction of elevated intraocular pressure.	30.03.16
8	Each Hard gelatin capsule contains: Rosuvastatin calcium IP Eq. to Rosuvastatin (as film coated immediate release tablet)+ 5mg/10mg Choline Fenofibrate IP Eq. to Fenofibric acid (as delayed release tablets) 135mg/135mg	For the treatment of mixed dyslipidemia.	16.06.16
9	α-Ketoisoleucine Calcium salt 67.0mg + α-Ketoleucine Calcium Salt 101.0mg + α-Ketophenylalanine Calcium Salt 68.0mg + α-Ketovaline Calcium Salt 86.0mg + α-Hydroxymethionine Calcium Salt 59.0mg + Lysine acetate 105.0mg (=75mg lysine) + Threonine 53.0mg + Tryptophan 23.0mg + Histidine 38.0mg + Tyrosine 30.0mg Film coated tablets	----	16.06.16
10	Each Hard Gelatin Capsules contains: Rosuvastatin Calcium Eq. to Rosuvastatin (as film coated tablet) + 20mg/20mg Aspirin (as enteric coated tablet) 75mg/150mg (Additional strength)	For the treatment of dyslipidemia associated with atherosclerotic arterial disease.	08.08.16

Note: The above list of FDC s is prepared as per the records available with the office of DCG (I).

**List of new drugs approved by New Drug Division, CDSCO from 01st Jan 2016 to till date<sup>10</sup>**

S. No.	Name of the drug	Indication	Date of issue
1	Nintedanib soft gelatin capsule 100/150mg (Nintedanib ethane sulfonate)	For the treatment of Idiopathic pulmonary Fibrosis.	11.03.16
2	Cisatracurium Besylate Bulk & 2 mg/ml	As an adjunct to general anesthesia.	14.03.16
3	Fomepizole bulk & Fomepizole injection 1.5mg/Ampoule	As an antidote for ethylene glycol OR Methanol ingestion.	14.03.16
4	Tofacitinib Tablets 5mg (Tofacitinib citrate)	For the treatment of rheumatoid arthritis.	01.04.16
5	Ceftroline Fosamil Injection 600 mg/Vial	For the treatment of community acquired pneumonia.	09.05.16
6	Panobinostat Hard Gelatin Capsules 10mg/20mg/15mg (Panobinostat lactate)	For the treatment of patients with community acquired pneumonia.	27.05.16
7	Bepotastine Besilate Bulk & Bepotastine Besilate 1.5%w/v Ophthalmic Solution	For the treatment of itching associated with allergic conjunctivitis	08.06.16
8	Ibutilide Bulk + amp; Ibutilide Fumarate Injection 0.1mg/ml	For the rapid conversion atrial fibrillation or atrial flutter of recent onset to sinus rhythm.	10.06.16
9	Acotiamide Hydrochloride Bulk + Tablet 100mg	For the treatment of bloating after meals, epigastric bloating and early satiety in functional dyspepsia.	06.07.16
10	Sacubitril+Valsartan film coated tablets 50mg/100mg/200mg	To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure and reduced ejection fraction.	14.07.16
11	Lurasidone Hydrochloride Bulk & Lurasidone Hydrochloride Tablets 40mg/80mg	For the treatment of patients with Schizophrenia	18.07.16
12	Fenticonazole Nitrate vaginal capsules 600mg	For the treatment of vulvovaginal candidiasis	10.08.16
13	Palbociclib Capsules 75mg/100mg/125mg	---	11.08.16
14	Midodrine Hydrochloride 2.5 mg Tablet	For the treatment of symptomatic orthostatic hypotension	02.09.2016
15	Phospholipids Fraction from Bovine Lung (surfactant) 50 mg/vial	Preventive use in premature neonates with a high risk of respiratory Distress Syndrome	12.09.2016

**CONCLUSION**

The government banned FDC drugs, extending to about 6,000 brands, on 10 March 2016, citing health risks, based on a report by a six-member committee headed by Chandrakant Kokate. The Kokate panel, which submitted its report on 20 January 2015, termed 963 FDCs "irrational, posing health threats. According to industry estimates, the current ban is expected to impact the Rs.98,000 crore pharmaceutical industry in India by about Rs.3,800 crore a year. Pharma companies soon moved the high court. Pfizer was the first to be granted a stay on the ban of its cough syrup Corex. The high court said the government action appeared hasty and arbitrary. The pharmacist should play an active role in patient education of such banned and approved drugs regularly and then play a key role in maintain healthy India.

**REFERENCES**

1. World Health Organization (2003). Introduction to drug utilization research (PDF). Geneva: World Health Organization. p. 33. ISBN 924156234X.
2. HCPC - Health and Care Professions Council - Education [Internet]. Hpc-uk.org. 2016 [cited 28 September 2016]. Available from: <http://www.hpc-uk.org/education/>
3. <https://www.pwc.in/assets/pdfs/pharma/PwC-CII-pharma-Summit-Report-22Nov.pdf>
4. Manish Panchal C. Success strategies for Indian pharma industry in an uncertain world [Internet]. Business-standard.com. 2016 [cited 28 September 2016]. Available from: [http://www.business-standard.com/content/b2b-chemicals/success-strategies-for-indian-pharma-industry-in-an-uncertain-world-114021701557\\_1.html](http://www.business-standard.com/content/b2b-chemicals/success-strategies-for-indian-pharma-industry-in-an-uncertain-world-114021701557_1.html)
5. Fixed dose combinations [Internet]. Apps.who.int. 2016 [cited 28 September 2016]. Available from: [http://apps.who.int/prequal/info\\_applicants/Guidelines/info\\_for\\_applicants\\_guidelines\\_fds.htm](http://apps.who.int/prequal/info_applicants/Guidelines/info_for_applicants_guidelines_fds.htm)
6. Gautam C and Saha L. Fixed dose drug combinations (FDCs): rational or irrational: a view point. British Journal of Clinical Pharmacology. 2008; 65(5): 795-796.
7. Prudhivi R, Barman AK, Mahanta PJ, Mangala L and Maddi R. Collection, Detection, Assessment, Monitoring and Prevention of Adverse Drug Reactions in the Nephrology Department of Gauhati Medical College and Hospital, Assam, India. Global Journal of Medical Research. 2014; 14(3B): 29-33.



8. Egazette.nic.in. 2016 [cited 28 September 2016]. Available from: [http://egazette.nic.in/\(S\(dxym3psmmtqbneyr4wlnagj0\)\)/EnhancedSearch.aspx](http://egazette.nic.in/(S(dxym3psmmtqbneyr4wlnagj0))/EnhancedSearch.aspx)
9. <http://www.cdscn.nic.in/writereaddata/Approved%20FDC%20list%20till%20july%202016.pdf>

Central Drugs Standard Control Organization [Internet]. Cdsco.nic.in. 2016 [cited 28 September 2016]. Available from: <http://www.cdscn.nic.in/forms/list.aspx?lid=2034&ld=11>