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An Investigation into the Reasoning for the Ban on Fixed Dosage Combinations

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Abstract
Either a single treatment or the sequential administration of multiple medications can be used to treat an aberrant situation. Utilising fixed dose combinations—specific dosage forms including two or more medications is another strategy. A fixed dose combination is a pharmacological administration method that combines two or more active ingredients into one. Because of all the benefits these products offer, prescribers and consumers alike are quite interested in using them. There are unavoidable intrinsic disadvantages as well. Popular antibiotics, pain relievers, and multivitamins are among the 156 FDC medications that the Health Ministry has prohibited over safety concerns. By outlawing certain potentially dangerous drug combinations, the government hopes to safeguard the public's health. The health concerns connected with these pharmaceuticals have led to their prohibition on production, marketing, and distribution, according to a gazette notice published by the Health Ministry on August 21, 2024. The prohibited FDCs included in the notice include antibiotics, anti-allergic drugs, painkillers, multivitamins, and fever and hypertension combo therapies. This article examines both the advantages and disadvantages of FDCs associated with the ban by the Government of India, as outlined in the gazette. The primary focus is on identifying the underlying causes for the ban.

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Keywords: FDC, Fixed dose combination, Ban on FDC, Advantages of FDC, Disadvantages of FDC

Introduction

Pharmaceutical companies are manufacturing FDCs in response to heightened demand from consumers and prescribers. When considering fixed-dose combinations (FDCs), one must account for aspects such as drug-drug interactions, adverse effects, the absence of necessity for additional components when a solitary prescription suffices, and the challenges in identifying the drug component in the FDC in cases of toxicity. Despite the numerous advantages of FDCs, their disadvantages cannot be disregarded. These drugs are synthetic, originating from compounds, each of which possesses specific physical and chemical properties. Any augmentation will unequivocally alter some or all of these attributes. The addition of one medication to another can alter the indications, contraindications, adverse effects, dosage, mechanism of action, and duration of action for each drug. A systematic and precise examination is essential due to its implications for health and life [1].

To be more specific, what are FDC medicines? Cocktail drugs are another name for fixed-dose combination drugs, which are also known as FDC drugs. These treatments are typically referred to as cocktail drugs. The formulation of these pharmaceuticals involves the combination of two or more active pharmacological ingredients in a predetermined proportion. The prohibition of the 156 FDCs was declared by the Union Health Ministry on August 12, 2024, following the release of a gazette notification from the ministry [2]. Products that incorporate one or more active ingredients and are designed for specific indications are referred to as fixed dose combinations (FDC). Table 1 enumerates the distinct categories applicable to FDCs [3].

Due to public health concerns, the government has prohibited the production, sale, and distribution of the specified FDCs in line with Section 26 A of the Drugs and Cosmetics Act of 1940. Table 2 presents a compilation of banned FDCs [4]. The simultaneous administration of Paracetamol and Ibuprofen. Paracetamol is categorized as an analgesic, denoting its capacity to relieve pain.

Table 1: Different categories applicable to FDCs

Group I	FDCs that contain one or more novel drugs as active components fall into the first category.
Group II	For a specific claim, active chemicals that have already been approved or marketed separately are combined for the first time in the second set of FDCs. In these cases, there is a high likelihood of significant pharmacodynamic or pharmacokinetic interaction between the components.
Group III	The third category of FDCs consists of those that are currently on the market but for which a new therapeutic claim or a modification to the active ingredient ratio is suggested.
Group IV	The fourth category of FDC consists of medications whose individual active components (or medications from the same class) have been used extensively for years in a specific indication or indications, their concurrent use is frequently required, and no claim is made other than convenience. It must be shown that the suggested dosage form is stable and that there is little chance of a pharmacological or pharmacokinetic interaction between the constituents. For these FDCs, extra animal or human data are typically not needed.

Table 2: Banned drugs list (FDCs) dated 02.8.2024 (Issue date - 12.08.2024 and published on 21.08.2024)

S. No.	Fixed Dose Combinations(FDCs)
1.	Amylase + Protease + Glucoamylase + Pectinase + Alpha Galactosidase + Lactase + Beta-Gluconase + Cellulase + Lipase + Bromelain + Xylanase + Hemicellulase + Malt diastase
2.	Antimony Potassium Tartrate + Dried Ferrous Sulphate
3.	Benfotiamine + Silymarin + L-Ornithine L-aspartate + Sodium Selenite + Folic acid + Pyridoxine hydrochloride
4.	Bismuth Ammonium Citrate + Papain
5.	Cyproheptadine HCl + Thiamine HCl + Riboflavine + Pyridoxine HCl + Niacinamide
6.	Cyproheptadine Hydrochloride + Tricholine Citrate + Thiamine Hydrochloride + Riboflavine + Pyridoxine Hydrochloride
7.	Rabeprazole Sodium (As enteric coated tablet) + Clidinium Bromide + Dicyclomine HCl + Chlordiazepoxide
8.	Fungal Diastase + Papain + Nux vomica Tincture + Cardamom Tincture + Casein Hydrolysed
9.	Mefenamic Acid + Paracetamol Injection
10.	Omeprazole Magnesium + Dicyclomine HCl
11.	S-adenosyl methionine + Metadoxine + Ursodeoxycholicacid BP + L-Methylfolate Calcium eq. to L-Methylfolate + Choline bitartrate + Silymarin + L-ornithine Laspartate + Inositol + Taurine
12.	Silymarin + Thiamine Mononitrate + Riboflavin + Pyridoxine HCl + Niacinamide + Calcium pantothenate + Vitamin B12
13.	Silymarin + Pyridoxine HCl + Cyanocobalamin + Niacinamide + Folic Acid
14.	Silymarin + Vitamin B6 + Vitamin B12 + Niacinamide + Folic acid + Tricholine Citrate
15.	Sodium Citrate + Citric Acid Monohydrate Flavored with Cardamom Oil, Caraway Oil, Cinnamon Oil, Clove Oil, Ginger Oil + Alcohol
16.	Sucralfate + Acelofenac
17.	Sucralfate + Domperidone + Dimethicone
18.	Sucralfate + Domperidone
19.	Tincture Ipecacuanha + Tincture Urgenia + Camphorated Opium Tincture + Aromatic Spirit of Ammonia + Chloroform + Alcohol
20.	Ursodeoxycholic Acid + Metformin HCl
21.	Weak Ginger tincture + Aromatic Spirit of Ammonia + Peppermint Spirit + Chloroform + Sodium Bicarbonate + Compound Cardamom + Alcohol
22.	Sucralfate + Pantoprazole Sodium + Zinc Gluconate + Light Magnesium Carbonate
23.	Aloe + Vitamin E Soap
24.	Povidone Iodine+ Metronidazole + Aloe
25.	Azelaic acid + Tea Tree Oil + Salicylic acid + Allantoin + Zinc oxide + Aloe vera + Jojoba oil + Vitamin E + Soap noodles
26.	Azithromycin + Adapalene
27.	Calamine + Aloes + Allantoin
28.	Calamine + Diphenhydramine Hydrochloride + Aloe + Glycerine + Camphor
29.	Chlorphenesin + Zinc oxide + Starch
30.	Clindamycin Phosphate + Zinc acetate
31.	Gamma Benzene Hexachloride + Benzocaine
32.	Glucosamine hydrochloride + Diacerein + Menthol + Camphor + Capsaicin
33.	Hydroxyquinone 2.0%w/w + Octyl Methoxycinnamate 5.0% w/w + Oxybenzone 30 % w/w
34.	Ketoconazole +Zinc Pyrithione +D-Panthenol +Tea Tree Oil +Aloes
35.	Ketoconazole +Aloe vera+ Vitamin A Acetate
36.	Ketoconazole +Aloes + ZPTO
37.	Kojic acid +Arbutin + Octinoxate + Vitamin E + Mulberry
38.	Lornoxicam + Capsaicin +Menthol+ Camphor
39.	Lornoxicam + Thiocolchicoside +Oleum Lini +Menthol + Methyl salicylate
40.	Menthol + Aloe vera Topical Spray
41.	Menthol +Lignocaine HCl +Aloe vera gel + Clotrimazole + Diphenhydramine

42.	Miconazole nitrate + Gentamicin + Fluocinolone Acetonide + Zinc Sulphate
43.	Miconazole + Tinidazole
44.	Minoxidil + Aminexil + Alcohol
45.	Minoxidil + Azelaic acid + Saw palmetto
46.	Minoxidil + Aminexil
47.	Pine Bark extract + Kojic acid + Sodium Ascorbyl Phosphate
48.	Povidone Iodine + Tinidazole + Zinc sulphate
49.	Povidone Iodine + Ornidazole + Dexpanthenol
50.	Salicyclic acid +Aloe vera+ Allantoin +D-Panthenol
51.	Silver sulphadiazine + Chlorhexidine Gluconate solution + Allantoin + Aloe vera gel + Vitamin E
52.	Sodium salicylate + Zinc gluconate + Pyridoxine HCl
53.	Tetracycline + Colistin Sulphate
54.	Clomiphene + Ubidecarenone
55.	Combikit of Clomiphene Citrate + Estradiol Valerate
56.	Flavoxate HCl + Ofloxacin
57.	Clomiphene Citrate + N-Acetylcysteine
58.	Primerose Oil + Cod liver oil
59.	Sildenafil Citrate + Papaverine + L-Arginine
60.	Tranexamic acid + Mefenamic acid + Vitamin K1
61.	Divalproex Sodium + Oxcarbazepine
62.	Divalproex Sodium + Levetiracitam
63.	Ergotamine tartrate + Caffeine + Paracetamol + Prochlorperazine maleate
64.	Piracetam + Ginkgo biloba extracts + Vinpocetin
65.	Ginkgo biloba + Methylcobalamin
66.	Ginkgo biloba + Methylcobalamin + Alpha lipoic acid + Pyridoxine HCl
67.	Ginseng Extract + Dried extract of Ginkgo Biloba
68.	Meclizine HCl + Paracetamol + Caffeine
69.	Nicergoline + Vinpocetine
70.	Gamma Linolenic Acid + Methylcobalamin
71.	Beclomethasone Dipropionate + Neomycin Sulphate + Clotrimazole + Lignocaine HCl
72.	Boric acid + Phenylephrine HCl + Naphazoline Nitrate + Menthol + Camphor
73.	Naphazoline HCl + Chlorpheniramine Maleate + Zinc Sulphate + Hydroxy Propyl Methyl
74.	Chlorpheniramine Maleate + Naphazoline HCl + Zinc Sulphate + Sodium Chloride + Hydroxy Propyl Methyl Cellulose
75.	Chlorpheniramine Maleate + Naphazoline HCl + Hydroxy Propyl Methyl Cellulose
76.	Chlorpheniramine Maleate + Sodium Chloride + Boric Acid + Tetrahydrozoline HCl
77.	Chlorpheniramine Maleate + Phenylephrine HCl + Antipyrine
78.	Ketorolac Tromethamine + Chlorpheniramine Maleate + Phenylephrine HCl + Hydroxy Propyl Methyl Cellulose
79.	Ketorolac Tromethamine + Flurometholone
80.	Naphazoline HCl + Zinc Sulphate + Boric Acid + Sodium Chloride+ Chlorpheniramine Maleate
81.	Naphazoline HCl + Hydroxy Propyl Methyl Cellulose + Boric Acid + Borax + Menthol
82.	Naphazoline HCl + Hydroxy Propyl Methyl Cellulose + Chlorpheniramine Maleate +Boric Acid + Sodium Chloride + Zinc Sulphate
83.	Naphazoline HCl + Hydroxy Propyl Methyl Cellulose + Chlorpheniramine Maleate +Boric Acid
84.	Naphazoline HCl + Chlorpheniramine Maleate + Methyl Cellulose
85.	Naphazoline HCl + Hydroxy Methyl Cellulose + Boric Acid + Menthol + Camphor
86.	Naphazoline HCl + Boric Acid+ Menthol+ Camphor + Methyl Cellulose + Chlorpheniramine Maleate + Zinc Sulphate + Sodium Chloride
87.	Naphazoline HCl + Phenylephrine HCl+ HPMC + Chlorpheniramine Maleate + Menthol + Camphor
88.	Naphazoline HCl + Hydroxy Propyl Methyl Cellulose + Chlorpheniramine Maleate + Boric Acid + Sodium Chloride + Zinc Sulphate + Menthol + Camphor
89.	Naphazoline HCl + Hydroxy Propyl Methyl Cellulose + Chlorpheniramine Maleate + Boric Acid + Zinc Sulphate
90.	Naphazoline HCl + Azelastine HCl+ Sodium Carboxy Methyl Cellulose + Menthol + Camphor + Stabilized Oxychlorocomplex
91.	Naphazoline HCl + Sodium Carboxy Methyl Cellulose + Menthol + Camphor + Stabilized Oxychloro complex
92.	Naphazoline Nitrate + Chlorpheniramine Maleate + Phenylephrine HCl + Hydroxy Methyl Cellulose + Boric Acid + Menthol+ Camphor
93.	Naphazoline Nitrate + Chlorpheniramine Maleate + Zinc Sulphate + Boric Acid + Sodium
94.	Norfloxacin + Tinidazole (with Betacyclodextrin) Eye ointment
95.	Ofloxacin + Beclomethasone Dipropionate + Lignocaine HCl
96.	Naphazoline HCl + Chlorpheniramine Maleate + Phenylephrine HCl + Menthol + Camphor
97.	Phenylephrine HCl + Naphazoline HCl + Menthol + Camphor + Hydroxy Propyl Methyl Cellulose
98.	Phenylephrine HCl + Naphazoline HCl + Menthol + Camphor
99.	Sulphacetamide Sodium + Zinc Sulphate + Chlorpheniramine Maleate + Boric acid + Sodium Chloride
100.	Zinc Sulphate + Boric acid + Naphazoline HCl + Sodium Chloride + Phenyl Ethyl Alcohol
101.	Cetirizine HCl + Paracetamol + Phenylephrine HCl
102.	Cetirizine HCl + Phenylephrine HCl
103.	Levocetirizine + Phenylephrine HCl
104.	Levocetirizine + Phenylephrine HCl + Paracetamol

105.	Phenylephrine HCl + Paracetamol + Levocetirizine HCl + Menthol
106.	Levocetirizine HCl + Ambroxol HCl + Paracetamol
107.	Levocetirizine HCl + Ambroxol HCl + Phenylephrine HCl
108.	Diethylcarbamazine Citrate + Chlorpheniramine maleate
109.	Diethylcarbamazine Citrate + Levocetirizine HCl
110.	Ambroxol HCl + Phenylephrine HCl + Guaiphenesin
111.	Bromhexine HCl + Phenylephrine HCl
112.	Etofylline + Theophylline anhydrous eq. to Theophylline hydrate + Ambroxol HCl
113.	Etofylline + Theophylline anhydrous eq. to Theophylline hydrate+ Montelukast
114.	Ambroxol HCl + Terbutaline Sulphate + Ammonium Chloride + Guaiphenesin + Menthol
115.	Ambroxol HCl + Salbutamol Sulphate + Ammonium Chloride + Guaiphenesin + Menthol
116.	Cetirizine HCl + Terbutaline Sulphate + Ambroxol HCl + Guaiphenesin
117.	Dextromethorphan Hydrobromide + Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate + Menthol
118.	Salbutamol Sulphate + Bromhexine HCl + Guaiphenesin + Ammonium Chloride + Menthol
119.	Terbutaline Sulphate + Bromhexine HCl + Chlorpheniramine Maleate
120.	Chlorpheniramine Maleate + P.G Sulphonate + Ammonium Chloride + Sodium Citrate + Menthol
121.	Aminophylline + Ammonium Chloride + Sodium Citrate
122.	Paracetamol + Chlorpheniramine Maleate + Phenyl Propanolamine
123.	Trithioparamethoxyphenyl Propene + Chlorpheniramine Maleate
124.	Aceclofenac 50 mg + Paracetamol 125 mg oral liquid
125.	Aceclofenac 50mg + Paracetamol 125 mg tablet
126.	Adenosine triphosphate diphosphate + Magnesium Orotate
127.	Amoxicillin Trihydrate + Dicloxacillin Sodium + Lactobacillus
128.	Camylofin Dihydrochloride 25 mg + Paracetamol 300mg
129.	Cefixime + Acetyl Cysteine
130.	Cephalexin Monohydrate + Serratiopeptidase
131.	Cetyl Myristoleate + Glucosamine Sulphate Potassium + Methyl Sulfonyl methane
132.	Diacerin IP + Glucosamine Sulphate Potassium Chloride USP + MSM (Methylsulphonyl Methane) + Cetyl Myristoleate
133.	Paracetamol+ Diclofenac Potassium + Caffeine Anhydrous
134.	Diclofenac sodium + Thiocolchicoside Injection
135.	Doxycycline + Ornidazole + Bromelain + Lactobacillus Rhamnosus + Lactobacillus Reuteri RC
136.	Doxycycline HCl + Betacyclodextrin + Serratiopeptidase
137.	Erythromycin stearate eq.to Erythromycin + Lactic acid Bacillus
138.	Etodolac + Paracetamol + Serratiopeptidase
139.	Flupirtine Maleate 400 mg + Paracetamol 325 mg tablet
140.	Glucosamine sulphate potassium chloride 410 mg + Chondroitin Sulphate 100 mg
141.	Glucosamine sulphate potassium chloride + Methyl Sulphonyl Methane (MSM) + Sodium Borate + Copper Sulphate pentahydrate + Manganese Sulphate + Vitamin D3
142.	Glucosamine Sulphate + Sodium chloride + Manganese + Boron + Zinc + Copper
143.	Glucosamine sulphate + Chondroitin sulphate + Methylsulfonylmethane + Vitamin D3 + Vitamin E + Vitamin C + Selenium + Elemental Zinc + Elemental Manganese + Elemental Chromium + Elemental Copper + Elemental Boron
144.	Glucosamine sulphate + Methyl sufonyl methane + Manganese sulphate + Vit E acetate + Calcium Carbonate
145.	Glucosamine Sulphate + Vitamin E acetate + Calcium Pantothenate + Vitamin D3
146.	Glucosamine Sulphate Potassium chloride + Calcium Carbonate from an organic source
147.	Cetyl Myristoleate + Glucosamine Sulphate Potassium chloride + Methyl sulfonyl methane
148.	Glucosamine Sulphate Potassium chloride + Methyl sulfonyl methane + Calcium carbonate + Vitamin E + Manganese
149.	Glucosamine Sulphate Potassium chloride + Calcium carbonate + Methyl sulfonyl methane + Vit D3
150.	Glucosamine Sulphate Potassium + Methyl sulphate Sodium + Sulphonyl Methane + Chondroitin Sulphate Sodium+ Calcium Carbonate + Vitamin D3+Sodium Borate + Cupric Oxide + Colloidal Silicon Dioxide + Manganese Chloride
151.	Methocarbamol + Diclofenac Sodium Injection
152.	Paracetamol + Pentazocin
153.	Sucralfate + Domperidone + Simethicone
154.	Sulfaquinoxaline + Diaveridine HCl + Vitamin K
155.	Tramadol HCl +Dicyclomine HCl + Domperidone
156.	Tramadol HCl + Paracetamol + Caffeine +Taurine

Antipyretic, meaning it has the ability to ward off fever. Ibuprofen, on the other hand, is classified as a non-steroidal anti-inflammatory drug, indicating that it works to reduce inflammation. This mixture works well for relieving acute pain related to a number of ailments, including toothaches and general body aches. A numerical reference has been supplied by the user [5].

The following are some of the overarching issues that are linked with FDCs and require care and consideration:

1. Concerns about fixed-dose combinations (FDCs) arise from changes in the pharmacokinetic profiles and half-lives of the constituent elements, which may necessitate alterations in the optimal dosage of one or more components.

2. Due to the numerous medication profiles contained in fixed-dose combinations (FDCs) and the variability of individuals' pharmacogenetic profiles during FDC manufacturing, FDCs may increase the risk of adverse drug reactions or drug-drug interactions.
3. Pharmacogenetic factors are particularly pertinent to fixed-dose combinations (FDCs) when the components are either essential for initiating the action of the relevant medications or are vital to the primary mechanism for their elimination.
4. The pharmacokinetic properties of fixed-dose combos (FDCs) are crucial in patients with infectious diseases, as combination therapy may raise concerns about resistance development.
5. Moreover, it is essential to evaluate the pharmacokinetic and pharmacodynamic characteristics of the substances while evaluating the elderly population, since their safety profiles may be altered.
6. Numerous studies have demonstrated that inadequate manufacture of Fixed-Dose Combinations (FDCs) may result in diminished efficacy or heightened toxicity during standard clinical application. Furthermore, these investigations have indicated that the optimal efficacy of FDCs may fluctuate over time, prompting concerns regarding their shelf life.
7. Fixed-dose combinations (FDCs) are associated with numerous additional concerns. One potential issue is the potential for FDCs to be priced at a higher rate than the sum of their individual components, unless there is a valid justification for the price disparity. An additional apprehension is that the addition of patents may result in the maintenance of elevated prices.
8. It can be difficult to pinpoint the precise ingredient in an FDC that is causing any potential negative effects. Finally, patients may receive either too little or too much of a particular substance due to difficulty in controlling the dosage.
9. Furthermore, fixed-dose combinations (FDCs) may lead to a less accurate diagnosis, especially when infections are involved, and may be less effective if patients do not follow the FDC's recommended regimen than if the individual components are administered separately.

The Central Government has banned 156 fixed-dose combination (FDC) medications that are deemed to have no therapeutic efficacy, as per a gazette notice. Fixed Dose Combinations (FDCs) are pharmacological combinations made up of one or more active ingredients that are used for certain indications, according to the Central Drugs Standard Control Organisation (CDSCO). With immediate effect, the ban has been put into place in accordance with recommendations made by an expert group that was formed to assess the efficacy of different drug combinations. The council of experts suggested that

1. There is no therapeutic basis for these FDCs, and the FDCs may pose a risk to human beings.
2. It is imperative to prohibit the manufacturing, sale, or distribution of these FDCs in order to protect the wider public interest [2, 6, 7].

The benefits of a fixed dose combination include:

- A reduction in the quantity of pills needed for therapy ¬ ease of administration.
- Pharmaceutical administration, and more especially its simplicity, is the subject of the current conversation.
- Lowers the rate of default and improves adherence.
- The bare minimum for prescription errors.
- The expense of treatment was cut in half.
- There is nothing complicated or difficult about the therapy plan.
- Medication ordering, planning, and management come with a host of logistical benefits.
- There are multiple components in the FDA-approved combination (FDC) that contribute to the overall therapeutic result. Medication safety and effectiveness have been proven in most cases where the Food and Drug Administration (FDA) has given its approval.
- Manufacturing and shipping costs for fixed-dose combos (FDCs) are lower than those for individual commodities when compared to production costs.
- This method guarantees that healthcare services are affordable, that patients comply to treatment procedures, and that the possibility of antibiotic resistance is reduced.
- Many illnesses and conditions, including diabetes, HIV/AIDS, malaria, and tuberculosis, which are acknowledged as major problems in world health, are treated with FDC medicines [5,8].

- **Negative aspects of FDCs**

A variety of interconnected challenges are brought about as a result of the creation of FDCs without the appropriate level of due diligence.

- When one medication has an additive or antagonistic action, the two components experience a pharmacodynamic mismatch that either reduces effectiveness or increases toxicity.
- Pharmacokinetic difference and the occurrence of maximum efficacy at different times point. Chemical incompatibility causing a drop in the lifetime of product stability.
- Drug interactions may arise from the metabolic pathways that are shared.

Although FDCs are widely available in a variety of treatment categories, a substantial number of these combinations can be regarded as unusual. The therapeutic categories that contain a significant number of fixed-dose combinations (FDCs) include preparations for cough, cold, and fever, analgesics and muscle relaxants, antimicrobials, medications for hypertension, dyslipidaemia, diabetes, and psychiatric disorders, as well as vitamins and minerals. The FDC formulation may contain a variable number of components, potentially exceeding five, irrespective of the rationale behind their inclusion or the quantity employed.

1. FDCs may not be safe to consume due to varying negative effects from specific constituents.
2. Putting two or more things together might occasionally introduce risks that were not there in the individual pieces.
3. When a patient experiences a bad reaction, it might be challenging to identify the underlying element.
4. Research indicates that combining medications is not always more effective than taking them alone.
5. Antibiotic resistance has rapidly increased in India due to the frequent usage of FDCs. The "ciprofloxacin-resistant - Salmonella typhi strains" example has made it difficult and costly to treat typhoid.

6. Drug companies thrive on strong demand and cheap production costs, resulting in significant profits.
7. If a person has a negative reaction to an FDC, it can be difficult to determine which active ingredient was the cause. This problem could be overcome by administering each medicine on its own and monitoring for negative effects. If no problems are detected, the medication can be transferred to an FDC.

The prohibition of Fixed Dose Combinations (FDCs) in India

1. The patient may not necessitate such a high quantity of medications, which could lead to an increased potential for adverse effects.
2. It is essential to individualise medicine doses, taking into account factors such as patient health, medical history, age, and sex.
3. Without obtaining sanction from the central government, numerous Indian companies have been marketing Fixed Dose Combinations (FDCs). The combination of azithromycin and cefixime, which has already been prohibited in the country, is an example of such an FDC.
4. It has been demonstrated that adding these unnecessary FDCs has negative consequences [5, 10].

Conclusion

FDCs offer a lot of advantages, but it is impossible to ignore their disadvantages. Pharmaceutical companies are producing FDCs in response to growing consumer and prescriber demand. Drug-drug interactions, side effects, the necessity of a single prescription in cases where several components are not needed, challenges in identifying the drug component in the FDC when toxicity occurs, and other considerations should be considered while talking about FDCs. Every now and then, the central government, after conferring with experts and suggesting modifications, issues a gazette ban on a significant number of FDCs. Despite the fact that an FDC should be carefully inspected before going on sale, this isn't actually the case. These drugs are artificial, made of chemicals, and all compounds possesses specific chemical and physical properties. It goes without saying that any addition will alter some or all of these qualities. The dosage, duration, mode of action, indications, adverse effects, and so on for any medication can change when it is combined with another. Since health and life are at stake, a thorough and precise study is required.

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