5. Status of fixed dose combination product as on MAY 2019

I. Status of 294 FDCs drug which were banned by DCGI in the 2007, CIPI got stay order fromC/ madras high court and , now after 12 years matter was recalled by " supreme court of India and accepted the report of DTAB as per court decision of 15-12-2017 DTAB recommended as

I. There are 83 FDCs consider as rational. The list of these 83 FDCs is enclosed: as

LIST OF 83 FDCs which were considered as Rational	
Sr. no.	Name of FDC
1	Acelofenac + Serratiopeptidase
2	Acelofenac + Tramadol
3	Acetaminophan + Codine phosphate
4	acetylcysteine + Selenomethionine +CholineBitartrate +Pyridoxine +Folic Acid + Vitamin E + Cyanocobalamin+ Chromium Nicotinate + manganese sulfate+ Zinc Sulfate
5	Adenocylcobalamine + Carbonyllon+ folic acid + Zincascorbate
6	Adenocynocobalamine+ Carbonyliron+Folluic acid
7	Alendronate sodium+ Calcium Carbonate +Vit-D3
8	Alendronate sodium+ cholicalceferol+ CalciumCitrate + Magnesium Hydroxide
9	Amlodipine + Lovastatin
10	Atenolol+ Hydrochlorothiazide+Amiloride
11	Atorvastatin+Acetyl Salicylic acid
12	Atorvastatin+Aspirin+ Ramipril
13	Atorvastatin+Mecobalmine+Folic acid
14	Atorvastatin+ Mecobalmine+Folic acid+Vit-B6
15	Atorvastatin+ Ramipril
16	Benfotimine + Pyridoxine+ Mecobalamine+ inositol+ Alphalipoic acid
17	Cefadroxyl+ Ambroxol
18	Cefixime+ ambroxol+lactic acid
19	Chlorzoxazone+ Nimesulide
20	Clorzoxazone+Paracetamol
21	Clindamycin+ clotrimazole+ Metronidazole
22	Clonidine+ Chlorthalidone
23	Clonidine+ Hydrochlorothiazide
24	Clopidogrel+Aspirin+ Atorvastatin
25	Diclofenacpotassium+ Serratiopeptidase

26	Diclofenacsodium+ Rabeprazole
27	Diclofenac + famotidine
28	Diclofenac +Meththylsalicylate+Linoleicacid+ Menthol
29	Diclofenac + Tizanidine
30	Dicyclomine+ Mefenamiacid+ Paracetamol
31	Domperidone+ Ranitidine
32	Drotaverinehydrochloride+Mefenamic Acid
33	Gabapentin+ Mecobalamin+ Thioctic acid
34	Gabapentin+ Mecobalamin+ Thioctic acid+folic Acid+ Pyridoxine
35	Gabapentin+ Mecobalamin+Pyridoxine +folic Acid
36	Ibuprofen+ Carisoprodol
37	Ibuprofen+ Codeine
38	Ibuprofen+Dextropropoxyphene
39	Ibuprofen+ Paracetamol+ Caffeine
40	Ibuprofen+ Pseudophedrine+Chlorpheniramine maleate
41	Ibuprofen+Tizanidine
42	Lansoprazole+ Amoxycillin+ Clarithromycin
43	Lansoprazole+ Amoxycillin+ Tinidazole
44	Lansoprazole+Domperidone
45	Lansoprazole+Tinidazole+ Clarithromycin
46	Levocetrizine+ Montelukast
47	Levofloxacin+Ambroxol
48	Levofloxacin+Ornidazole
49	Losartan + Perindopril
50	Mebeverine+ PlantagoOvata
51	Mecobalaminalphalipoicacid+ Folic acid + Vit-b6+ Choline
52	Mecobalamine+ Alphalipoic acid
53	Mecobalamine+ Alphalipoic acid+ Folic acid
54	Mecobalamine+ Alphalipoic acid+ Vit-b1+ Folic acid
55	Mecobalamine+Biotin
56	Mecobalamine+CalciumPantothenate
57	Mecobalamine+Folic acid
58	Mecobalamine+Vit-A+Vit-E+Vit-C+Vit-B1+Vit-B6+Vit-D3+Selenium
59	Mecobalamine+Vit-b1+Vit-b2+Vit-b6+Folic acid
60	Mecobalamine+Vit-b1+Vit-B6+Folic acid+Alphalipoic acid
61	Mecobalamine+Vit-b1+Vit-b6+Nicotinamide+ D-panthenol
62	Mefenamicacid+ Dicyclomine
63	Meloxicam+Paracetamol
64	Metformin hydrochloride+ Mecobalamine
65	Methocarbamol+ Ibuprofen
66	Methocarbamol+Nimesulide

67	Methocarbamol+Paracetamol
68	Methoclopramide hydrochloride+Paracetamol
69	Mupirocin+ Metronidazole
70	Naproxen+Domperidone
71	Norfloxacin+ Ornidazole
72	Norfloxacin+ Tinidazole+Lactobacillus
73	Ofloxacin+Metronidazole
74	Ofloxacin+Ornidazole+Lactobacillus
75	Ofloxacin+Prednisolone
76	Ofloxacin+Tinidazole
77	Paracetamol+Dicycloverine+ Mefenamic
78	Pegabalin+ Mecobalamine
79	Pegabalin+ Mecobalamine+Pyridoxine+Thioctic Acid+Folic Acid
80	Pegabalin+Thioctic Acid+Folic Acid+Pyridoxine
81	Roxithromycin+ Ambroxol
82	Roxithromycin+Carbocisteine
83	Satranidazole+Ofloxacin

Following procedure is required for the approval of 83 drugs

a) The applicant shall submit form 44 mentioning dosage form and strength (duly filled, signed and stamped) along with treasury challan of INR 15,000 for each FDC.
b) Name and Composition of FDC
c) Copy of product permission issued by SLA to any firm prior to 28.11.2007 as documentary evidence.
d) Copy of manufacturing license in form 25/28 and form 29 for manufacturers who are not holding product permission from SLA and want to apply for these FDCs
e) S.No. of FDC as per the list available on website.
f) Stability studies data (06 months accelerated data of 03 batches) and
g) Test specification of the FDC along with method of Analysis

All the manufacturers who are already holding licenses from state Licensing Authorities for such FDCs and did not obtain NOC from DCG (I) are required to submit their applications to this Directorate at the earliest but not later than 4 months, failing which their application will not be considered and their licenses will be considered as without legal validity.

In view of above, you are requested to direct all concerned stakeholders of your state to follow above procedure for clearance of the cases.

80 FDCs were banned by notifications on January 2019 and 49 FDCs were identified for Clinical Trails and PMS studies earlier. 17 more FDCs were identified following data provide was considering in adequate to prove its rationality 'CFDS'.

Now will you know C "for FDC approved

6.

Regarding 344 FDCs which has been banned by DGCI under section 26 (A), after this immediately, we approach Delhi high court and took stay order that was granted by Delhi high court but later on, ministry of health challenged this Delhi high court stay order in supreme court of India., 15 FDC which were approved before 1988 shall be continue for manufacturing and marketing.

However, far remaining drugs ie. 329 Supreme Court directed the ministry of health to re-verify by committee of DTAB.

DTAB declare 329 drugs have no Therapeutic value. Therefore be banned by Ministry of Health.

7.

Regarding approximate 2540 FDCs were declare rational drugs by Coktae committee.

Out of 2540 FDCs 1600 FDCs were sent to SLA/SDC with the direction that if any manufacture applied for approval same can be given on the conditions mentioned below.

a) The applicant shall submit form 44 mentioning dosage form and strength (duly filled, signed and stamped) along with treasury challan of INR 15,000 for each FDC.
b) Name and Composition of FDC
c) Copy of product permission issued by SLA to any firm prior to 28.11.2007 as documentary evidence.
d) Copy of manufacturing license in form 25/28 and form 29 for manufacturers who are not holding product permission from SLA and want to apply for these FDCs
e) S.No. of FDC as per the list available on website.
f) Stability studies data (06 months accelerated data of 03 batches) and
g) Test specification of the FDC along with method of Analysis

Special Note

As mention above in paragraph 5. and 7., fees applicable is shown 15000 preproduct now as per current notification FSR227E fees structure has been changed as ANX 1. Now these drugs are trated new drugs.