File No.04-01/2013-DC(Misc. 13-PSC Part-III)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 31 MAR 2023

NOTICE

Subject: Evaluation of 16 Fixed Dose Combinations (FDCs) by DTAB Sub-committee which were earlier considered as irrational in the Expert Committee report of the Prof. Kokate committee-regarding.

The 86th meeting of the Drugs Technical Advisory Board (DTAB) was held under the Chairmanship of the Director General of Health Services. It deliberated on the report of Prof. Kokate Committee with respect to Fixed Dose Combinations (FDCs) considered as irrational in the Expert Committee report of the committee.

DTAB examined the Expert Committee report of Prof. Kokate dated 12.03.2021 in its 86th DTAB meeting and in principle agreed to the recommendations of the Prof. Kokate Committee and recommended that the sub-committee under Dr. Nilima Kshirsagar, Emeritus Scientist, Former Chair in Clinical Pharmacology, ICMR, Mumbai, shall examine the 16 irrational FDCs in details as per the earlier procedures.

In order to give an opportunity to the manufacturers of said FDCs and the concerned stakeholders for presenting the precise data with respect to these FDCs, the Subcommittee has desired that the manufacturers and other stakeholders submit the information in the prescribed format as per **Annexure 'A'** (along with supporting documents) which is enclosed herewith for further action.

Accordingly, all the manufacturers of said FDCs and the concerned stakeholders are hereby requested to submit the information in the prescribed format and the relevant supporting documents in hard copy as well as soft copy (i.e. in C. D.Form) to this office latest by 30th April 2023 till 5:00 PM.

(B.K.Samantaray)
Deputy Drugs Controller (India)

Copy to:
1. Dr. Nilima Kshirsagar, the Chairperson, Sub-Committee of DTAB
2. Indian Drug/Pharmaceuticals Association Forum
3. Website of CDSCO for information and necessary action by manufacturers of said FDCs and concerned stakeholders

Annexure A – March 2023

FDC Identification number as on the website:

Format for submission of information on FDC to DTAB Sub-Committee

(Submit all the information including full text of references as hard copy as well as soft copy)

S. No.	Item	Response	
1a.	(a) Composition of Product (FDC): (Details of all ingredients, strengths /dosage forms)		
	(b) Brand name/s if any:		
	(c) Name and Address of the Applicant Whether the applicant is i. Manufacturer: ii. Marketer : iii. Any other (please specify) : iv. --		
1b.	Licensing authority with year of license and informations, if any submitted to Licensing Authority while obtaining the License	Name and Designation of the licensing Authority	Date &Year of Product License
1c.	Whether the FDC is approved by DCGI, If so details/evidence thereof		
1d.	Whether the FDC is Pre 1988, If so details/evidence thereof		

S. No.	Item	Response
2.	Particulars of the drug: Dosage form, composition of the formulation (including all active ingredients)	
3.	Indication(s)	
4.	Provide a copy of the approved Package insert that is currently provided	
5.	State the category under which FDC approval is claimed as per Drugs and Cosmetics Rules.	
6.	Pharmacological classification	
7.	a) Therapeutic justification / rationale for each ingredient and quantity contained in the FDC	
	b) Therapeutic value claimed or purported to be claimed of the FDC (Postulated advantage/ Therapeutic value of FDC)[Tick (√) appropriate option(s)]	
	i. Increased efficacy	
	ii. Reduced incidence of adverse effects	
	iii. Dose reduction	
	iv. Reduced cost	
	v. Booster for another drug	
	vi. Improved patient adherence/ Convenience	
	vii. Minimization of abuse of other actives	
	viii. Reduced development of microbial resistance	
	ix. Any other (please specify)	
	c) Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five relevant full text articles in peer-reviewed journals/ relevant information from textbooks	
8.	Pharmacokinetic/ pharmacodynamics rationality with half-life details of individual ingredients, dosage schedule of individual drugs and dosage schedule of FDC (Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five most relevant full text articles in peer-reviewed journals/ relevant information from textbooks)	

S. No.	Item	Response
9.	Published data regarding safety and efficacy of FDC (Submit a one-page summary with highest level of evidence, supporting the claim of postulated advantage/rationale. The evidence should be enclosed in the form of maximum of five most relevant full text articles in peer-reviewed journals/ relevant information from textbooks)	
10.	Safety & Efficacy data if any, regarding the FDC, generated by the applicant (Submit a one-page summary. Also submit the article based on these data, if published or one-page abstract of each study if unpublished with CTRI number if available)	
11.	Please specify the guidelines National/international/ professional Association/Chapters/bodies) if any, that have recommended the use of the above FDC or use of the ingredients thereof concurrently	
12.	a) Whether marketed in EU, UK, Canada, Australia, Japan and the USA?	
	b) If yes, which country/countries?	
	c) Specify country-wise product brand name, ingredients, dosage form, its strength, amount of usual ingredients per dosage form, indication/s and dosage frequency	
13.	Regulatory status of the FDC in other countries	
13.1	Countries where the drug is:	
	(a) Marketed	
	(b) Approved	
	(c) Approved as IND	
	(d) withdrawn, if any, with reasons	
13.2	Restrictions on use, if any, in countries where marketed/approved	
14.	Specimen of labels and cartons	
15.	Any other relevant information	
16.	Submit one page summary of grounds and reasons in support of FDC with not more than 5 relevant references	
17.	Submit PPT of presentation in hard copy (Maximum 7 slides) which the company will present to the committee	

(Note: Individual Form shall be submitted for each FDC and all above information shall be provided for each strength/ dosage in the same Form of FDC)

Signature of the Authorized representative: _____

Name: _____

Designation: _____

Date: _____

Place: _____

For Office Use:	
Identification No.	

List of 16 FDCs in 294 FDCs recommended as irrational by Prof. Kokate Committee.

Sl.no.	Name of FDC
1.	Acetyl salicylic acid + Ethoheptazine
2.	Aloe extract + Allantoin + Alphatocopherol acetate + D-Panthenol + Vitamin A
3.	Aloe extract + Vitamin E + Dimethicone + Glycerine
4.	Aloe vera + Jojoba oil + Vitamin E
5.	Aloe vera + Orange oil
6.	Aloe vera + Jojoba oil + Wheat germ oil + Tea tree oil
7.	Aloe vera + Vitamin E + Herbal
8.	Dicyclomine + Paracetamol + Clidinium Bromide
9.	Dicyclomine + Paracetamol + Clidinium Bromide + Chlordiazepoxide
10.	Gliclazide + Chromium Picolinate
11.	Paracetamol + Lignocaine
12.	Amoxicillin + Serratiopeptidase + Lactobacillus Sporogens
13.	Amoxicillin + Cloxacillin + Lactic acid bacillus + Serrapeptase
14.	Amoxicillin + Serratiopeptidase
15.	Cefadroxyl + Probenecid
16.	Cefuroxime + Serratiopeptidase