Recommendations of the 64thSEC (Cardiovascular & Renal) made in its meeting held on 07.05.2019 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory Remarks			
New Drug Division			
1	12-01/18-DC(Pt-07)/PU-030 Enoxaparin Sod. Inj	M/s Sanofi India Ltd.	The firm presented the proposal to update the package insert of Enoxaparin Sod. Inj. After detailed deliberation the committee recommended for approval of the proposal to update the package insert of Enoxaparin Sod. Inj.
2	12-01/18-DC(Part-319) Esmolol&Dexmeditomidine	Dr. Shamilajalgawonlkar	The committee opined that the proposal should be discussed in SEC(Analgesic and Anesthesia)
3	12-07/16-DC(Pt-C) FDC of Azelnidipine 8mg/16mg + Metoprolol succinate ER 50 mg tablets	M/s Ajanta	The firm was not ready for presentation.
4	12-05/18-DC Azlendipine 8mg/8mg+ olmesartan 20/40 mg	M/S Hetero Labs Ltd.	The firm presented the proposal before the committee for conducting BE study as well as Phase III Clinical trial. After detailed deliberation the committee recommended for grant of permission to conduct the BE study. Results of the BE Study should be submitted for further consideration of the clinical trial proposal.
5	12-05/18-DC (Pt-B) Azlendipine 8mg/8mg+ Telmisartan 20/40 mg	M/S Hetero Labs Ltd.	The firm presented the proposal before the committee for conducting BE study as well as Phase III Clinical trial. After detailed deliberation the committee recommended for grant of permission to conduct the BE study. Results of the BE Study should be submitted for further consideration of the clinical trial proposal.
6	12/01/19-DC/PU-020 Indapamide(Package insert)	M/s Serdia Pharma	The proposal should be examined in upcoming SEC meeting and the firm should make presentation.
FDC Division			
7	4-10/2018-DC Metoprolol succinate IP eq. to Metoprolol tartrate (ER)+Cilnidipine+Telmisartan IP (47.5mg/50mg+10mg+40	M/s. Ajanta Pharma	The firm presented the BE as well as Phase III Clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture & market the FDC for the treatment of uncontrolled essential

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
	mg) Film coated tablet		hypertension with stable ischemic heart disease.
8	4-39/2018-DC (Pt. Emcure) Amlodipine+Telmisartan IP (2.5mg/5mg+40mg/40mg) tablet	M/s. Emcure Pharmaceuticals	Firm presented their proposal before the committee. After detailed deliberation the committee recommended for approval of the protocol amendment.
9	FDC/MA/19/000032 Amlodipine Besylate 2.5mg/5mg + AzilsartanKamedoxomil 40mg/40mg tablet	M/s.Emcure Pharmaceuticals Ltd.	Firm presented their proposal for conduct of BE study with waiver of clinical trial. After detailed deliberation the committee recommended for conduct of BE study as per the protocol. The committee also recommended that the Phase-III Clinical trial should be conducted for which Clinical trial protocol should be submitted for review by the committee.
10	FDC/MA/19/000044 AzilsartanKamedoxomil eq. to AzilsartanMedoxomil40 mg/40mg + Chlorthalidone IP 6.25mg/12.5mg + Cilnidipine IP 10mg/10mg film coated tablet	M/s. Akums Drugs & Pharmaceuticals	Firm presented their proposal for conduct of BE study as well as Phase-III clinical trial. After detailed deliberation the committee recommended for grant of permission to conduct BE Study. The BE study results shall be presented before the committee for further review. As regard to Phase –III Clinical trial, the committee recommended to submit the revised protocol in respect of inclusion criteria, Exclusion criteria, lab tests etc.,
Medical Device Division			
11	CI/MD/2018/7210 Promesa™ DES	M/s Meril Life Sciences Pvt. Ltd., Gujarat	The firm has presented the clinical trial protocol. After detailed deliberation the committee recommended for grant of permission to conduct clinical trial with the condition that the sample size should be increased to 50 patients and pre discharge laboratory blood tests should be incorporated in the protocol.
12	4-MD/CT-76/2011-DC On-X and St.Jude Heart valve	M/s. I process clinical marketing pvt. ltd.,	In light of earlier recommendations of the committee dated 27.03.2018 and 31.10.2018, firm presented their proposal for amendment in protocol with respect to change in follow up period. After detailed deliberation the committee opined that there is no substantial, scientific justifiable reason to amend the follow up period.
BABE Division			
13	12-09/2019/BA-BE/Misc-20/DC	M/s Raptim Research	The firm presented the BE study protocol. After detailed deliberation, committee

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Olmesartanmedoxomil 40mg+Amlodipine 10mg+Rosuvastatin 20mg+Ezetimibe 10mg		opined that the firm should submit justification/rationale for this combination.