Recommendations:-

The **34th SEC (Cardiovascular & Renal)** meeting deliberated the proposals on **08.11.2016** and recommended the following:

Agenda No	File Name &Drug name, Strength	Firm Name	Recommendations
Subsequent New Drug Division Proposals			
1	12-100/2016-DC(Pt-Astrazeneca-SND) Ticagrelor tablet 60mg (Import and Marketing & Firm requested for Phase III Waiver)	M/s Astrazeneca	Firm presented the proposal before the committee. Ticagrelor 90mg tablet is already approved in India. The proposed additional strength I,e) Ticagrelor 60mg for the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with a history of myocardial infarction (MI occurred at least one year ago) and a high risk of developing a thrombotic event is approved internationally. The committee recommended for proposed additional strength and indication without local clinical trial.
2	12-85/2016-DC(Pt-Centaur-Snd) Potassium Chloride prolonged release tablet 750mg (Manufacturing and Marketing permission of a modified release dosage form)	M/s Centaur Pharmaceuticals Pvt. Ltd	The firm presented the proposal before the committee. The committee after detailed deliberation recommended a clinical trial for the proposed product.
3	12-35/2016-DC(Pt-Astellas-SND) Tacrolimus 3mg prolonged release hard gelatine capsule (Import and Marketing with local CT Waiver)	M/s Astellas Pharma	The firm presented the proposal before the committee. The firm is already holding Import registration certificate from DCGI for 0.5 mg, 1.0 mg, 5 mg prolonged release hard gelatine

Agenda No	File Name &Drug name, Strength	Firm Name	Recommendations
			capsules in India. The Firm presented justification for the additional strengths of 3 mg PR capsule. After detailed deliberation the committee recommended for the proposed strength, which is intermediate to the already approved strengths.Hence the committee recommended the additional strength without local CT subject to comply of following :- The Firm has to comply to the CDSCO Office letter dated 05.09.2016.
4	12-113/2016-DC(Pt-Cadila-SND) Rosuvastatin Tablet 15mg/30mg (Additional Strength)	M/s Cadila	The firm presented the proposal before the committee.The firm is already holding Manufacturing permission from office of DCGI for 5 mg, 10 mg, 20 mg, 40 mg tablets in India. The Firm presented justification for the additional strengths of 15mg & 30mg tablets. After detailed deliberation the committee recommended for the proposed strengths, which are intermediate to the already approved strengths.Hence the committee recommended the additional strengths without local CT .
Medical Devices Division Proposals			
5	4-MD/CT-168/2016-DC Application for permission to conduct Clinical Trial titled **"Melange™ BRS - Sirolimus**	**M/s. Meril Life sciences Pvt. Ltd,** Bilakhia House., survey No.135/139, Muktanand Marg	The firm presented the protocol for Melange BRS I. After detailed deliberation the committee suggested the following:

Agenda No	File Name &Drug name, Strength	Firm Name	Recommendations
	Eluting BioResorbable Peripheral Scaffold System" under Drugs & Cosmetics Act and Rules (NEW MEDICAL DEVICE)	chala, vapi - 396191	1).In inclusion criteria the patient with renal artery stenosis > 70 % to be enrolled. 2)Decrease in creatinine more than 20 % should be taken for defining the efficacy in terms of the renal function. 3)The follow up angiography should be done after 9 -12 months. 4)The imaging to be repeated at the conclusion of the study at 3 years. The firm should submit the revised protocol accordingly for approval.
6	31-1579-MD/2014-DC Application for approval of updated indication for the products viz. **Promus Elemental Plus Monorail Everolimus Eluting Coronary Stent System, Promus Premier Everolimus Eluting Platinum Chromium Coronary Stent System and Synergy™ Monorai™ Everolimus Eluting Pt Cr Coronary Stent System** under the provisions of Drugs & Cosmetics Act and Rules (UPDATED INDICATION)	M/s Boston Scientific India pvt. Ltd, C-41 Ground Floor, Okhla Industrial Area, Phase-II, New Delhi-110020	The Firm Presented the case, After detailed deliberation , the committee observed that a large amount of data has been accumulated to approve the inclusion of following indication for The PROMUS Element Plus & Promus Premier • Coronary Bifurcation Lesions • Coronary artery ostial lesions • Unprotected left main coronary artery lesions • Coronary artery total occlusion lesions • In-stent restenosis in coronary artery lesions **For Synergy:** • Acute Coronary Syndrome • Unstable Angina • Renal Failure • Coronary Bifurcation

Agenda No	File Name &Drug name, Strength	Firm Name	Recommendations
			Lesions • Coronary Multi-vessel Disease • Coronary Saphenous Vein Graft Lesions • Coronary artery ostial lesions • Unprotected left main coronary artery lesions • Coronary artery total occlusion lesions • In-stent restenosis in coronary artery lesions The committee recommended for the approval of proposed additional indications.
New Drug Division Proposals			
7	12-48/12-DC Efonidipine hydrochloride tablets 10mg/ 20mg/ 40mg (Phase III Clinical Trial & Bio Equivalence study report)	M/s. Zuventus Healthcare Ltd.	The Firm Presented the Clinical Trial and BE study data from Phase III Clinical Trial conducted in the country. After detailed deliberation, the committee recommended for grant of approval for marketing the drug in the country.