Recommendation:-

The MDAC (Cardiovascular) deliberated the proposals on 17/01/2014 and recommended the following:-

Agenda No.	File No.	Name of the Firm& Name of the Proposed product	Recommendations
1.	4-MD/CT-104/2013-DC)	M/s St Jude Medical India Private Limited, No. 1-11-250/A, Matarani Sensation, Lane Beside's Syndicate Bank, Begumpet, Hyderabad- 500016 Product- Enlightn Renal Artery Ablataion Catheter	The committee deliberated the matter and observed that the said product "Enlightn renal Artery Ablation catheter is CE marked and clinical trial already done in Greece & Australia on 46 subjects. The committee recommended that said the perrisssion for conducting clinical trial may be considered with a condition that firm is required to submit amended protocol comprising an Audio-video informed consent form, compensation details, Ethics Committee approval etc., as per the requirement of Schedule Y of Drugs and Cosmetics Rules and latest guidelines issued by CDSCO.
2.	4-MD/CT-108/2013-DC	M/s. Meril Life Sciences Pvt. Ltd., Bilakhiya House, Muktanand Marg, Chala, Vapi-396191, Gujrat Product- MeRes™ Sirolimu Eluting Bioresorbable Vascu Scaffold System	The committee has deliberated the matter and recommended that firm is required to submit the following documents:- 1 Detailed safety and efficacy data in animals including pharmacokinetic data required to be submitted to DCGI. 2 The trial is investigative in nature and the complete cost to the patient has to be borne by the sponsor. 3 The sponsor should clarify

			and follow the compensation guidelines as laid out by the DGC (I). 4. The sponsor should clarify the financial support for the study, the contract details with the investigators with regard to the payment fees as per the CDSCO norms. In view of above human trial permission may be considered after clarification on the Animal studies submitted to DCG (I)
3	4-MD/CT-88/2012-DC	M/s. Cook India Medical Devices Pvt. Ltd., 4/249A, Rasim Enclave, Poonamallee High Road, Goparasanallur, Kattupakkam, Chennai-600056 Product- Zilver PTX Drug Eluting Peripheral Stent	The committee has deliberated the matter and recommended that the proposed product may be registered in India for marketing with a condition to conduct phase IV clinical study in India. The trial protocol to be reviewed by MDAC-cardiovascular experts.
4	31-1258-MD/2013-DC	M/s. Biorad Medisys Pvt. Ltd., having warehouse at # 394, Khata No. 660, 1st Floor, Eshwari Industrial Estate, Bannerghatta Road, Bangalore 560076 Product: 1.Spiroflex Thrombectomy Set 2. Spiroflex VG Thrombectomy Set 3.AVX Thrombectomy Set 4.Solent Omni Thrombectomy Set 5.Solent Prox Omni Thrombectomy Set	The firm was not able to attend the meeting. Hence the proposal may be discussed in next MDAC cardiovascular meeting.

5	31-1165-MD/2012-DC	M/s. Clairvoyance Consulting, Flat No. 801, 8th Floor, Indra Prakash Building, 21 Barakhamba Road, New Delhi- 110001 Product: TAPAS ("Targeted Adjustable Pharmaceutical Administration System")	The committee deliberated the matter and recommended that the proposed product may be registered in India for marketing with a condition to submit Post Marketing Surveillance data as per the requirements of Schedule Y of Drugs and Cosmetics Rules.
6	31-890-MD/2011-DC (End.-01)	M/s Johnson & Johnson Ltd., J-I, Shree Arihant Complex, VitthalNer, Thane Bhiwandi Road, District-Thane, Bhivandi Product Relieva Stratus Ethmoid and Frontal Microflow Spacer	The committee has deliberated and observed that the product Relieva Stratus Ethmoid and Frontal Microflow Spacer is a low risk class- I device and the said device is already approved in USA and firm has also holding the CE design approval certificate for the said devicesThe committee recommended that there is no need to carry out the Clinical trial in Indian population Hence permission for registration certificate may be granted.
7.	29/Misc/3/2013-DC(149)	M/s. India Medtronic Pvt. Ltd., Mohan Co-operative Industrial Estate Ltd., New Delhi-110044 Transcatheter Core Valve (TCCV) for Personal Use	The committee has deliberated the matter stating that M/s India Medtronichas applied for the grant of Registration certificate for the Product 'Core valve' and the firm was asked to carry out the Phase III Clinical trial in India to establish the safety and Efficacy in Indian Population Thereafter the firm has not carried out the Phase III Clinical trial in India, however it has been observed that firm is promoting the said product in

			India through the Import of the product under the Personal License. Hence committee recommended that the same may be brought to the notice of Ministry of Health and Family welfare for necessary action.

Recommendation:-

The MDAC (Cardiovascular) deliberated the proposals on 27.09.2013 and recommended the following:-

Agenda No.	File No.	Name of the Firm & name of proposed products	Recommendations
1.	4-MD/CT-76/2011-DC	M/s iProcess Clinical Marketing Pvt., Ltd., Bangalore. 1. On-X Prosthetic Heart Valve (Aortic & Mitral) 2. SJM Mechnical Heart Valve (Aotic & Mitral)	MDAC has again reviewed the proposal total 1000 patients to be enrolled at 25 different sites globally and 300 patients will be enrolled at 8 sites in India Out of 8 sites 4 are Government Institutes The device will be provided free of cost by the firm. Recommendation made by the MDAC dated 18.09.2012 have been complied and submitted amended protocol accordingly They are complying with the requirements for quality the permission to conduct phase IV clinical trial They agreed to provide compensations as per CDSCO guidelines and procedure related complications are also included in compensations. Follow up will occur at discharge, 3 months, 6 months 1years and annually therafter during the conduct of study for at least 5 years. - Hence permission may be granted. The committee recommended for the grant of permission to conduct phase IV trial

2.-	4-MD/CT-90-2012-DC	M/s Emergo (India) Consulting Pvt., Ltd., Hyderabad DEsyne Novolimus Eluting Coronary Stent System	The DEsyne Stent systems incorporated an ultra thin durable polymer coating and low Novolimus drug dose (5mcg/mm). the committee after deliberation recommended that the Novolimus coated stent is not approved in India. clinical trial is required to be conducted in Indian population
3	29/Misc/03/2012-DC (143)	M/s Emergo (India) Consulting Pvt., Ltd., Hyderabad Atricure Cryo Modulo System & Atricure Ablation System	The committee recommended that the product Atricure Synergy Abalation System and Atricure Cryo Modulo Syetm are not covered under the notified categories of medical devices and do not attract the provisions of D&C Act & Rules thereunder
4	CLAA/MD/GUJ/01/2008-DC (pt-II)	M/s Meril Life Science Pvt., Ltd., Gujarat Tapered Stent System for Biomime Epitome metaphor and Tapered PTCA Balloon Dilation	The Committee recommended that the permission may be granted
5	4-MD/CT-33/09-DC	Safety Update report	Safety Update report reviewed by committee and found in order

Recommendation:-

The MDAC (Cardiovascular) deliberated the proposals on 31.05.2013 and recommended the following:-

01	4-MD/CT-94/2013-DC	M/s Boston Scientific Pvt. Ltd. Watchman LAA device.	The committee after deliberation recommended that there is a need to see the import details and PMS data of similar devices approved by this office. The approval of said product may be considered for marketing in India with a condition to carry out Phase IV trial as per Schedule Y of Drugs and Cosmetics Rules and satisfactory verification of the Phase IV trial data.
02	4-MD/CT-93/2013-DC	M/s Heart Cure Pharma Services Pvt. Ltd., Mumbai 'Biodegradable Patent DuctusArteriosus (PDA) Occlusion device'	The committee has deliberated the matter and it has been observed that the preclinical data in terms of safety and efficacy is inadequate. Hence the committee recommended that the data should be re-presented by an expert i.e. preferably a cardiologist, after the preclinical safety concerns are addressed.
03	31-1057-MD/2011-DC	M/s Johnson & Johnson Ltd., 'Palmaz Genesis Peripheral Stent (sterile)'	The committee after deliberation recommended that there is need for taking input from Dr Sandeepsharma in said matter it has also been recommended to provide more detail/information of import and PMS data for the product 'Palmaz Genesis peripheral stent
04	4-MD/CT-52/2010-DC	M/s Fortis Escorts Taxus Study-Compensation regarding	The committee deliberated the matter and discussed the data regarding SAEs including Death. The committee has also examined the method and compensation paid found to be adequate.

Recommendations:-

The MDAC (Cardiovascular) deliberated the proposals on 30/06/2014 and recommended the following:-

Agenda No.	File No.	Name of the Firm & Name of the Proposed product	Recommendations
1	31-1258-MD/2013-DC	**M/s. Biorad Medisys Pvt. Ltd.,** having warehouse at # 394, Khata No 660, 1st Floor, Eshwari Industrial Estate, Bannerghatta Road, Bangalore 560076 **Products:** ***1.Spiroflex Thrombectomy Set*** ***2. Spiroflex VG Thrombectomy Set*** ***3.AVX Thrombectomy Set*** ***4.Solent Omni Thrombectomy Set*** ***5.Solent Proxi Omni Thrombectomy Set***	The committee has deliberated the matter and recommended that the firm is required to submit recent clinical data proving the efficacy of said product and usage data in respect of said product worldwide. The same data will be deliberated in next MDAC meeting for further review.
2	31-1120-MD/2012-DC	**M/s. Boston Scientific India Pvt. Ltd.,** 8th Floor, Tower A, Building No. 5, Cyber Terrace, DLF Cyber City, Phase-III, Gurgaon-122002, Haryana **Products:** ***FilterWire EZ Embolic Protection System (3.5mm – 5.5mm)***	The committee has deliberated the matter. The applicant stated that since the similar product is already approved and available in the market with the same indication, therefore, the committee considered the proposal however since the applicant has informed that earlier they have marketed in India till 2012 therefore, justification should be submitted by the applicant in this regard to this office.
3	4-MD/CT-93/2013-DC	**M/s. Heart Care Pharma Services Pvt. Ltd.,** Hall No. 2, Pakhade House, 48	The committee has deliberated the matter and recommended that the data produced by the

		Nehru Road, Vile Parle, Mumbai- 400057 **Product name:** ***Biodegradable Patent Ductus Arteriosus (PDA) Occlusion Device***	firm is inadequate and is not satisfactory therefore committee opined that the applicant need to represent again their case along with adequate pre clinical data before the experts of the MDAC Further the committee has also insisted that presenters should justify their case in more scientific manner
4	4-MD/CT-113/2014-DC	**M/s. Meril Life Sciences India Pvt. Ltd.,** Flat no 6E, 6th Floor, Vandana Building, 11 Tolstoy Marg, New Delhi-110001. **Products:** ***1. PULSECATH iVAC3L*** ***2. PULSECATH iVAC3L-ST (21 Fr.)***	The committee has deliberated the matter and recommended that the firm is need to conduct clinical trial on Indian population on minimum 30 patients as there is no any latest human clinical data Accordingly protocol need to present before MDAC for their further review
5	4-MD/CT-112/2013-DC	**M/s. Cook India Medical Device Pvt. Ltd.,** 4/249-A, Rasim Enclave P H Road, Goparasanallur, Kattupakkam, Chennai **Products:** ***Polyvinyl Alcohol Foam Embolization Particles***	The committee has deliberated and observed that since the product has already been in the market since long therefore their proposal may be considered
6	31-1057-MD/2011-DC	**M/s Johnson & Johnson Ltd.,** J-I, Shree Arihant Complex Vill, Kalher, Thane Bhiwandi Road, District- Thane, Bhivandi. **Product:** ***Palmaz Genesis Peripheral Stent (Sterile)***	The committee has deliberated and observed that the PMS data required to be submitted however the product is already being used in India earlier therefore the committee opined that the product permission can be considered

S.No.	Name & Designation of MDAC (Cardiovascular) experts	Signatures
1	Dr. V K. Bahl, Prof and Head, Department of Cardiology, AIIMS, Delhi	
2	Dr. Ajith Kumar, Cardiologist, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum Thiruvananthapuram - 695 011, Kerala, India	
3	Dr. V. K. Suri Head, Precision Engineering BARC, Mumbai	

Recommendations:-

The MDAC (Cardiovascular) deliberated the proposals on 21/10/2014 and recommended the following:-

Agenda No.	File No.	Name of the Firm & Name of the Proposed product	Recommendations
1.	31-1258-MD/2013-DC	**M/s. Biorad Medisys Pvt. Ltd.,** having warehouse at # 394, Khata No. 660, 1st Floor, Eshwari Industrial Estate, Bannerghatta Road, Bangalore 560076. **Products:** 1. **Spiroflex Thrombectomy Set** 2. **Spiroflex VG Thrombectomy Set** 3. **AVX Thrombectomy Se** 4. **Solent Omni Thrombectomy Set** 5. **Solent Proxi Omni Thrombectomy Set**	The firm did not turned up for the presentation.
2.	4-MD/CT-117/2014-DC	**M/s. India Medtronic Pvt. Ltd., Mumbai** **Product:** Micra Transcatheter Pacing System **Approval for: No Objection Certificate/Permission to conduct Clinical Study (Pivotal Study) in India for Micra Transcatheter Pacing System under Drugs & Cosmetics Act and Rules.**	The committee has deliberated the clinical trial protocol presented by the firm and recommended that the permission to conduct said clinical study in India may be granted.
3.	29/Misc./3/2014-DC (96)	**M/s. Meril Life Sciences India Pvt. Ltd.,** Flat no. 6E, 6th Floor, Vandana Building, 11 Tolstoy Marg,	The committee has deliberated the matter and recommended that as the said device is not yet approved and safety & efficacy

		New Delhi-110001. **Products:** **1. Cogent DES – Sirolimus Eluting Balloon Expandable Renal & Biliary Stent System** **2. Myra DES – Sirolimus Eluting Balloon Expandable Peripheral Stent System**	of the device need to be established before manufacturing & marketing in India. Therefore, the committee recommended that firm needs to submit clinical trial protocol to prove the safety & effectiveness of the device on statistically significant population; to DCG (I) for consideration & same would be placed before the committee for further review and taking further necessary action in the matter.
4.	4-MD/CT-113/2014-DC	**M/s. Meril Life Sciences India Pvt. Ltd.,** Flat no. 6E, 6th Floor, Vandana Building, 11 Tolstoy Marg, New Delhi-110001. **Products:** ***1. PULSECATH iVAC3L*** ***2. PULSECATH iVAC3L-ST (21 Fr.)***	The committee has deliberated the matter and recommended that the firm's application for waiver-off clinical trial of said product may not be considered.
5.	4-MD/CT-108/2013-DC	**M/s. Meril Life Sciences India Pvt. Ltd.,** Flat no. 6E, 6th Floor, Vandana Building, 11 Tolstoy Marg, New Delhi-110001. **Clinical Trial Study**: titled **"A prospective, multicentre, single arm, open label study of MeRes Sirolimus Eluting Bioresorbable Vascular Scaffold System (BVS) in the treatment of patients with *de novo* native coronary artery lesions".**	The committee has deliberated the animal data generated by the firm and found to be satisfactory. Further the committee recommended that said clinical trial permission may be granted to the firm as per the protocol presented by the firm.
6.	31-93-MD/2006-DC (Re.Reg.2009) (End.01)	**M/s. Edwards life Sciences (India) Pvt. Ltd, Techniplex II, 7th Floor, Unit No. 1 & 2, Off S.V.**	The device has already been approved in various countries i.e. US, Japan, Canada, EU etc. The data submitted shows that

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		Road, Goregaon West, Mumbai. **Products:** SAPIEN XT-Transcatheter Heart Valve with the Novaflex+ Transfemoral Kit	is safe and effective for its intended use. However the committee recommended to prove the safety and effectiveness of the device in Indian population, therefore, a Clinical trial study need to be conducted. The firm is required to submit the clinical trial protocol to DCG(I) for consideration & same would be placed before the committee for further review and taking further necessary action in the matter.
7.	4-MD/CT-54/2010-DC	**M/s. Escorts Fortis Heart Institute and Research Centre Ltd., Okhla Road, New Delhi.** **Clinical Trial Study titled:** **"TUXEDO – India: prospective, single blind, multi-centre, randomized trial to compare the TAXUS Element Coronary Stent System against the XIENCE Prime Coronary Stent system in the treatment of a Diabetic Patient Population in India".**	It may be referred to SAE-committee for further review.

S.No.	Name & Designation of MDAC (Cardiovascular) experts	Signatures
1.	**Dr. V.K. Bahl, Prof and Head,** Department of Cardiology, AIIMS, Delhi.	
2.	**Dr. Ajith Kumar,** Cardiologist, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum Thiruvananthapuram - 695 011, Kerala, India	

3.	**Dr. Sandeep Bansal,** Prof. And Head, department of Cardiology, VMMC & Safdarjung Hospital, Delhi	Bansal
4.	**Dr. Vijay Trehan,** Cardiologist, G.B. Pant Hospital, Delhi	