**Government of Pakistan**

**Drug Regulatory Authority of Pakistan**

**Ministry of National Health Services, Regulations & Coordination**

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**MINUTES OF THE 7TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**HELD ON 24TH OCTOBER, 2017**

 7th meeting of the Medical Device Board (MDB) was held in the Committee Room of Drug Regulatory Authority of Pakistan, TF Complex, G-9/4, Islamabad on 24th October, 2017. The meeting was chaired by Dr. Sheikh Akhter Hussain, Director Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan. The meeting was attended by the following:-

|  |  |  |
| --- | --- | --- |
| **S.No.** | **Name and Designation / Department** | **Position in the MDB** |
|  | Dr. Sheikh Akhter Hussain, Director Medical Devices & Medicated Cosmetics, DRAP, Islamabad. | Chairman |
|  | Mr. Akber JanChief Drug Inspector, Health Department, Khyber Pakhtunkhwa(Nominee of Director General Health, Khyber Pakhtunkhwa)  | Ex-officio Member |
|  | Syed Abdul Saleem,Chief Drug Inspector, Health Department, Balochistan(Nominee of Director General Health, Balochistan)  | Ex-officio Member |
|  | Brig. (R) Dilshad Ahmed Khan, Professor of Pathology & Director Research, National University of Medical Sciences, Rawalpindi. | Member |
|  | Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.  | Member |
|  | Mr. Muhammad Tahir AzizChief Operating Officer, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar. | Member |
|  | Brig.(R) Dr. Waqar Azim Niaz, Consultant Urologist & Transplant Surgeon, Quaid-e-Azam International Hospital, Golra Mor, Islamabad.  | Member |
|  | Dr. Ghazanfar Ali Khan, Deputy Director (MDMC),Drug Regulatory Authority of Pakistan,Islamabad. | Member/Secretary |

 The meeting started with the recitation of the Holy Quran.

**Item No. I.** **CONFIRMATION OF MINUTES OF 6TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**Decision:** The Board confirmed the minutes of the 6th meeting of MDB.

**Item No. II**. **UPDATE REGARDING THE PROVISIONAL ESTABLISHMENT CERTIFICATE (PEC) AND PRODUCT REGISTRATION ACKNOWLEDGEMENTS (PRA) ISSUED.**

 The Board was briefed regarding the Provisional Establishment Certificate (PEC) and Product Registration Acknowledgements issued as follow:

 On the directions of the Honorable Supreme Court of Pakistan on March 2, 2017 during Human Rights Case No. 623-P/2017, Prime Minister’s office convened two extensive meetings chaired by Secretary to the Prime Minister held on 6th March and 10th March, 2017 involving all the relevant stakeholders and as an outcome of these meetings, SRO. 167(I)/2017 was issued by the Federal Government dated 15-03-2017 for regulation of medical devices including cardiac stents. The salient features of the said SRO are as under:-

* The said SRO has a Schedule “A” of 134 life saving medical devices including cardiac stents, legalizing the import, sale and usage of these medical devices, if these were already approved for use and sale by regulatory authorities of USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherland, Norway, Spain, Sweden, Switzerland, UK or CE Mark by notified bodies of European Union.
* The said Notification empowered CEO, DRAP to amend the Schedule “A” from time to time.
* Schedule “A” devices cannot be imported, sold or used in Pakistan except from above sources.
* In addition, a firm has to submit provisional registration application along with original Free Sale Certificate.
* The previous SROs declaring medical devices as drugs are repealed.
* Medical Devices Board shall issue Provisional Establishment Certificate for a period of 06 months, within 07 working days, on submission of original valid authorized agency agreement.
* The rest of the medical devices, not included in the Schedule “A”, have been exempted from the operation of Medical Devices Rules, 2015 for six months.
* All medical devices registered as drug and qualifying above said criteria shall be deemed to be registered as medical device under the Medical Devices Rules, 2015.

 Medical Device Board in its 4th meeting convened on 24th March, 2017 approved application forms for grant of Provisional Establishment Certificate, application form for Provisional Registration of medical devices for import and Provisional Establishment Certificate. So far, **74** Provisional Establishment Certificates under this SRO have been issued to the applicant firms and **295** acknowledgements for Provisional Registration of medical devices have also been issued.

**Decision: The Board appreciated the efforts made so far by the Division of Medical Devices & Medicated Cosmetics and noted the information.**

**Item No. III**. **CURRENT STATUS OF AMENDMENTS IN MEDICAL DEVICES RULES, 2015.**

 The Board was briefed that Federal Government vide various SROs declared certain medical devices as drugs under Drugs Act, 1976 and were being regulated accordingly. These include disposable syringes, disposable infusion sets, blood transfusion sets, canula, catheter, stent, auto-disable syringe and butterfly needles.

 After devolution of Ministry of Health, Drug Regulatory Authority of Pakistan Act, 2012 was promulgated on 13th November, 2012 to regulate, manufacture, import, export, storage, distribution and sale of therapeutic goods which includes drugs, alternative medicines, medical devices, biologicals or other related products as may be notified by the Authority. All medical devices were brought under regulation. The Drugs Act, 1976 was made Schedule of the DRAP Act, 2012.

 For this purpose Medical Devices Rules, 2015 were notified on 9th March, 2015 with phase-wise implementation dates for four risk classes (A, B, C & D) from 1 year to 2 years. The dates were extended twice until 30th September 2016 for Class D and 8th December, 2016 for Class C medical devices.

 These rules are yet not practically implemented due to non-availability of Conformity Assessment Body (CAB) having scope of medical devices. Under these rules and as being done internationally in many countries, there is requirement of third party certification body i.e CAB for conduction of conformity assessment of medical devices and their manufacturers / importers and issuance of certificates thereof before applying for establishment license and registration of medical devices. These bodies were needed to be registered with Medical Device Board before conducting conformity assessment. Being a new system and subject, Two CABs applied for registration with DRAP but could not comply with the requirements yet. Even no CAB could get accreditation with PNAC with required scope.

 In the present stent issue in February, 2017, the Honorable Supreme Court of Pakistan has taken notice in Human Rights Case No. 623-P/2017 for use of sub-standard cardiac stents which were also sold on exorbitant rates. On the directions of the Honorable Supreme Court of Pakistan on March 2, 2017, Prime Minister’s office convened two extensive meetings chaired by Secretary to the Prime Minister held on 6th March and 10th March, 2017 involving all the relevant stakeholders.

 As an outcome of Prime Minister’s office meeting, a Committee including stakeholders under the chair of Additional Secretary, M/o National Health Services, Regulation and Coordination was constituted on 21st March, 2017 to review the existing Medical Devices Rules, 2015 in order to make them implementable. In this regard, after successive meetings and thorough deliberations, the committee proposed and drafted amendments in Medical Devices Rules, 2015 which were approved by the Authority in its 48th meeting held on 21st June, 2017. The [Committee for Revision](file:///F%3A%5Cmedical%20devices%20rules%20final%5Cattachments%5CCommittee%20for%20Revision.png) of medical devices rules had drafted the amendments in consultation with stakeholders and provinces. Comments were also invited on draft rules from M/O Commerce and FBR.

 Law & Justice Division re-casted it as amendments in Medical Device Rules, 2015 instead of vetting new draft Medical Devices Rules, 2017. In addition, Law & Justice Division during vetting has omitted the two provisions, namely, "Indenting of medical devices" and "Removal of ambiguities" with the comment that it is against the principal of law and further explained that the 'removal of ambiguities' will remain with Law & Justice Division and not with the Medical Device Board, as was proposed by the Committee. However, the clause of removal of ambiguities is concerned with technical difficulties and clarification for medical devices and not concerned with nature of rules.

 Later on, Healthcare Devices Association of Pakistan (HDAP) has shown its reservations on the draft rules vide letter dated 7th September, 2017. This required a final consensus development with the stakeholders on draft Rules, thus the final consultative meeting was held on 10-10-2017. The points agreed will now be incorporated in draft amendments and further actions shall be done accordingly.

**Decision:** The Board was briefed regarding following salient features of the amendments in the MDR, 2015:-

1. Rules in regards to Conformity Assessments Bodies for establishments licences and enlistment / registration of medical devices has been omitted; whereas GMP inspection of the manufacturing and establishments will be conducted by DRAP inspection panel both for local and foreign instead of CABs as the case may be.
2. The panel of inspectors of DRAP shall inspect the foreign manufacturers before grant of registration for countries other than provided in the notification. Exemption from inspection shall only be given to those products approved by the reference countries as provided in rules or pre-qualified by WHO.
3. Grouping of Medical Devices shall be as IMDRF and as per international practice has been made part of the Schedule which shall be amended by the MDB from time to time.
4. Life saving medical devices shall be imported from reference countries or WHO prequalified and CE marked by EU notified bodied directive EU 93/42/EEC.
5. Provision has been added for establishment of testing laboratories and Appellate laboratory for medical devices.
6. Provision for making an appeal before the Appellate Board, if aggrieved by the decision of the MDB has been added.
7. The panel of inspectors of DRAP shall endorse Good Distribution Practices for Medical Devices (GDPMD) for medical devices establishments having Drug Sale License.
8. Variation as approved in the country of origin shall be acceptable to the MDB as a variation change provided information as prescribed in Rules is submitted.
9. The Classification of medical devices shall be as per International Medical Device Regulator Forum (IMDRF) and has been made part of the Schedule which shall be amended by the MDB from time to time.
10. Fee for medical devices has been made part of the schedule which shall be amended by the Authority and Policy Board.
11. Class A medical devices shall be enlisted and Class B, C and D shall be registered.
12. Fee structure of medical devices taking into consideration the regional and international practices of Category A medical devices has been reviewed.
13. Indenting for import of medical devices shall be allowed for government institutes.

 The MDB was further informed that the provisions of "indenting of medical devices" for medical institutions and charitable organizations and "removal of ambiguities" on technical matters of medical devices by the MDB earlier removed by the Law & Justice Division have been modified and incorporated in the draft MDR, 2017. File has been sent to Ministry to be forwarded to Law and Justice Division for vetting and further processing accordingly.

**The Board appreciated the efforts made so far by the Authority and noted the information.**

**Item No. IV**. **DRAFT NOTIFICATION FOR EXTENSION IN EXEMPTION PERIOD FOR FURTHER PERIOD OF 2 MONTHS IN SRO 167(I)/2017.**

 In the present stent issue in February, 2017, the Honorable Supreme Court of Pakistan has taken notice in Human Rights Case No. 623-P/2017 for use of sub-standard cardiac stents which were also sold on exorbitant rates. On the directions of the Honorable Supreme Court of Pakistan on March 2, 2017, Prime Minister’s office convened two extensive meetings chaired by Secretary to the Prime Minister held on 6th March and 10th March, 2017 involving all the relevant stakeholders.

 As an outcome of these meetings, SRO. 167(I)/2017 was issued by the Federal Government dated 15-03-2017 for regulation of medical devices including cardiac stents. Under SRO. 167(I)/2017, the exemption period of medical devices not included in the Schedule “A”, has been expired on 15-09-2017. As the amendments in Medical Devices Rules, 2015 are under process, therefore, draft notification for extension in exemption period for further 2 months has been sent to Federal Government for its approval.

**Decision: The Board noted the information.**

**Item No. V**. **FREE SALE CERTIFICATE OF MEDICAL DEVICES**.

 Some regulatory authorities do not mention the validity on Free Sale Certificates of medical devices issued by them. The same matter was also discussed in the Registration Board in its 261st meeting and it was decided that

*"If the Free Sale Certificate does not contain the validity date, then the certificate shall be considered for 5 years from the date of issuance."*

**Decision: The Board decided that if the Free Sale Certificate of medical devices does not mention the validity date, then Free Sale Certificate shall be considered by MDB for 5 years from the date of issuance.**

**Item No. VI**. **DECISION REGARDING ALREADY LICENSED MEDICAL DEVICES UNITS.**

 The Board was briefed that the subject case was placed before the Medical Device Board in its 4th meeting for its consideration. Board decided as follows:-

"*The Board decided that Licensing unit shall be requested to handover all the files of medical devices manufacturing units with immediate effects and meanwhile the Board authorized its Chairman to constitute panels of inspectors for verification of current GMP status of the units."*

 In the light of above decision, the Licensing Unit was requested to handover the record of medical devices manufacturing units. The Licensing Division has provided the record of following manufacturing units of medical devices:-

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Lic No.** | **Name of Firm** | **Address** | **Management** | **Production Incharge (Date of approval)** | **QC Inchage (Date of approval)** | **License Validity Period** | Remarks |
| 000695 | M/s Injection System (Pvt) Ltd. | 271 Industrial Estate Gadoon Amazai. KPK | Change of management In-process | Subhan Ali 10/01/2017 | In-process | 09-09-2015 to 08-09-2020 | Shortcoming in Renewal application is conveyed to firm as per Drug (L,R,&A) rules 1976. |
| 000701 | M/s Lahore Medical Instruments (Pvt) Ltd. | 48-Km Lahore Kasur Road Kasur. Punjab | Kh. Asif Razee Sameena Shakir Muhammad Ghalib Razee Muhammad Arif Misbah Arif | Ahmad Zafar 25/02/2011 | In-process | 24-02-2016 to 23-02-2021 | Panel of inspector is constituted as per Drug ( L,R &A) Rules 1976 |
| 000704 | M/s Surgi Plast | Road No. L-4 Plot No. 78 Industrial Estate Gadoon Amazai , KPK | In-process | In-process | Arshid Ali 11/06/2011 | 11-06-2016 to 10-06-2021 | Application submitted and pending for panel constitution. |
| 000638 | M/s Amson Vaccines & Pharma (Pvt) Ltd. | 113-Industrial Triangle Kahuta Road Islamabad. | Shamim Ahmad KhanSaleem AsgharNauman Shamim | Sajjad Hussain 21/03/2014 | Irfana Jabbar 21/03/2014 | 07-08-2013 to 06-08-2018 | DML renewal issued |
| 000706 | M/s Frontier Pharmaceutical (Pvt) Ltd. | W-10 Industrial Estate Jamrud Road Hayatabad Peshawar  | Mujeeb AlamImdad HussainLliya Amjad | In-process | In-process | 11-06-2016 to 10-06-2021 | Shortcoming in Renewal application is conveyed to firm as per Drug (L,R,&A) rules 1976. |
| 000708 | M/s Armoz Pharma (Pvt) Ltd. | 22-Km Ferozepur Road Lahore | Manzoor Ellahi Taj Shehla Manzoor Umer Manzoor | In-process | In-process | 14-06-2016 to 13-06-2021 | Shortcoming in Renewal application is conveyed to firm as per Drug (L,R,&A) rules 1976. |
| 000709 | M/s Crespak Medical Industries  | 8-Km Manga Raiwind RoadLahore  | Muhammad AamirMuhammad Naeem AshiqMuhammad Asim Ashiq | In-process | In-process | 14-06-2016 to 13-06-2021 | Application submitted and pending for panel constitution. |
| 000710 | M/s Medicare Disposable Industries  | 4.5-Km Defense Road Kahna Nau Lahore | Sajjad Ahmad | In-process | In-process | 15-06-2016 to 14-06-2021 | Application submitted and pending for panel constitution. |
| 000717 | M/s Taj Syringes (Pvt) Ltd. | Plot No. 303A Gadoon Amazai Industrial Area Gadoon Amazai. KPK | In-process | In-process | Fida Muhammad | 13-06-2016 t0 12-06-2021 | Shortcoming in Renewal application is conveyed to firm as per Drug (L,R,&A) rules 1976. |
| 000756 | M/s Pak Disposable Syringes (Pvt) Ltd. | Plot No. L-5 Industrial Estate Gadoon Amazai KPK | Muhammad IqbalRashida Khanum | Tahira Yasmeen Qureshi | Muhammad Afeel Siddique 15/10/2012 | 15-10-2012 to 14-10-2017 | DML renewal issued |
| 000705 | M/s Al-Badar Manufacturing (Pvt) Ltd. | Plot No. 193/3 Road No. 7 Industrial Estate Gadoon Amazai District Swabi.KPK | In-process | Zia Ul Qadeer | In-process | 11-06-2016 to 10-06-2021 | Shortcoming in Renewal application is conveyed to firm as per Drug (L,R,&A) rules 1976. |
| Unlicensed | UNISA (pvt) Ltd | G.T road Noshehra, KPK | Muhammad Ismail,Najam ul saqib, Shah Fahad, Aqib Ismail | Nil | Nil | Nil | Under LOP approval |
| Unlicensed | NISA SF (pvt) Ltd | 10 Km shiekhupura mreedkey road, Punjab | Shi Baoshe, shi Mingyang,LI Jing,Muhammad wassi shah, Muhammad Inayat Ullah | Nil | Nil | Nil | LOP Approved |
| 000703(Invalid) | Japanz International (Pvt) Ltd | 6-Km, Gujranwala Road , Shiekhupura. | Syed Ghayoor abbas, Syed Muhammad Abu Talib. | Syed Aun Muhammad | Mr.Imran Saleem | 25-02-2011 to 24-02-2016 | DML is invalid due to non submission of DML renewal application till to date. |

The MDB was appraised about the files received from the Licensing division and their current situation. The process of licensing by Licensing division was also elaborated before the Board. Dr. Muhammad Tahir Aziz emphasized that feedback may be taken from institutions using locally manufactured medical devices regarding their safety and performance.

**Decision: After thorough deliberations the Board decided as follows:**

1. **The MDB decided to conduct new Establishment Licence inspection, Establishment Licence renewal inspection and cGMP inspection of above firms in order to determine the manufacturing status of the firm through panel of inspectors/experts constituted by Chairman MDB. The Board also directed to get the record copy of those firms which contain the facility of both the Drugs and Medical devices.**
2. **The Board assigned the task to Dr. Muhammad Tahir Aziz to design the performa for obtaining feedback from institutions using locally manufactured medical devices regarding their safety and performance which shall be presented before MDB for its approval in next meeting. Mr. Ghayour Ahmed, Assistant Director was nominated as focal person to coordinate with Dr. Muhammad Tahir Aziz and to communicate the Performa to all the quarter concerned.**

**Item No. VII**. **DELEGATION OF POWERS FOR DAY-TO-DAY WORKING OF MDMC REGARDING INSPECTIONS**

For day-to-day working of MDMC regarding local and foreign inspection of Manufacturing and Importing units for Grant, Renewal of Establishment License, Medical Device Registration and routine GMP/GDP inspections, the power of constituting panel of inspectors/experts may be delegated to Chairman MDB for smooth and efficient working of the division.

**Decision: The Board delegated the powers to Director MDMC to perform above functions.**

**Item No.VIII**. **EXTENSION IN ALREADY ISSUED PROVISIONAL ESTABLISHMENT LICENSE**

The importing firms were issued Provisional Establishment certificates for a period of six months as per SRO 167 (I)/2017. Some of these license has been expired or going to expire shortly. Furthermore, it is submitted that draft notification for extension in exemption period for further period of validity of two months w.e.f 15-9-2017 has been sent to Federal Government for its approval. The importers are facing difficulties for import of medical devices due to expiry of their provisional establishment certificates.

**Decision: The Board decided that those firms whose PECs have expired or will expire shall be regularized as per SRO.167(I)/2017 after its extension period.**

**Item No. IX**. **DELEGATION OF POWERS REGARDING ISSUANCE OF CLEARANCE CERTIFICATE FOR IMPORT OF MEDICAL DEVICE(s), COMPONENT OR RAW MATERIAL(S).**

 It is submitted that as per rule 97 of Medical Device Rules, 2015 (S.R.O 204(1)/2015) stated as under:

 "NO person shall import any medical device or any component thereof or any raw material thereof for manufacturing medical device unless authorized by the Authority or any officer or body authorized in this behalf by it with approval of the Board."

 Similarly Rule 102(1) of Medical Device Rules, 2015( S.R.O 204(1)/2015) states that " No medical device or component or raw material for manufacturing medical device shall be released from the customs unless a clearance certificate has been obtained by the importer from an officer authorized in this behalf ".

 The importers are facing difficulties in getting clearance of medical devices, components and Raw material(s) from Custom Authorities as they demand clearance certificate from authorized officer in this regard.

**Decision: After detailed deliberation and discussion the MDB delegated the powers for issuance of import permits and clearance certificate for import of medical device or any component thereof or any raw material under Medical Devices Rules to Area Assistant Directors of each province to be exercised through Officer Incharge /Additional Director of field offices of DRAP.**

**Item No. X**. **CHANGE OF MANUFACTURING SITE.**

 M/s ACP Systems , Karachi had informed that the following products manufactured by M/s Medtronic, Inc, 710 Medtronic Parkway, NE Minneapolis, Minnesota 55432 USA has been registered in the their name as drug:

|  |  |  |
| --- | --- | --- |
| **S.No.** | **Name of Medical Device** | **Registration No.** |
|  | Sprinter Legend RX Balloon Dilatation Catheter | 071622 |
|  | Sprinter NC/SC RX Balloon Dilatation Catheter | 071623 |
|  | Endeavor Resolute (DES) Coronary Stent  | 071624 |
|  | Endeavor Sprint (DES) Coronary Stent | 071625 |
|  | Resolute Integrity DES Coronary Stent  | 071626 |
|  | Integrity BMS Coronary Stent | 071627 |

Later on, Principal manufacturer M/s Medtronic USA changed the manufacturing sites as below:-

|  |  |  |  |
| --- | --- | --- | --- |
|  | Sprinter Legend Rapid Exchange Balloon Dilatation Catheter | 071622 | *Legal Manufacturer:*M/s Medtronic, Inc.710 Medtronic Parkway, Minneapolis, MN 55432, USA.*Manufacturing Site:*M/s Medtronic Mexico S.de R.L.de CV, Av, Paseo Cucapah 10510 EI Lago, C.P. 22210 Tijuana, Baja California, Mexico. |
|  | Sprinter NC/SC Rapid Exchange Balloon Dilatation Catheter | 071623 |
|  | Endeavor Resolute (DES) Coronary Stent  | 071624 | *Legal Manufacturer:*M/s Medtronic, Inc.710 Medtronic Parkway, Minneapolis, MN 55432, USA.*Manufacturing Site:*M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland. |
|  | Endeavor Sprint (DES) Coronary Stent | 071625 |
|  | Resolute Integrity DES Coronary Stent  | 071626 |
|  | Integrity BMS Coronary Stent | 071627 |

 Applications submitted on 02-08-2012 aimed to change of manufacturing site. The firm has requested that manufacturing site of their already registered products may be changed accordingly.

 It is submitted that for change of manufacturing site the firm has provided Free Sale Certificate (Embassy attested) from regulatory authority of Ireland for above products. Approval letter of USFDA is also provided for Serial No.2,4,5& 6 but site is not mentioned. Furthermore, the name of product at serial No.2 in the Free Sale Certificate is NC Sprinter Rapid Exchange Balloon Dilatation Catheter. Fresh Fee of Rs. 50,000 provided by the firm for each product and also applied for renewal of above products within time.

 The case was placed in 267th meeting of Registration Board and the Board decided as follow:-

"Approved new manufacturing site along with legal manufacturer and decided to issue approval letter with correct name of above products along with sizes/codes as per free sale certificate."

 The approval letter of change of manufacturing site was put up for issuance but could not be issued as SRO 167(I)/2017 was issued on 15-03-2017 wherein SROs declaring stents and catheters was repealed and above approval by Registration Board was granted under Drugs Act, 1976 while stents and catheters are now being dealt as medical devices.

**Decision: The Board examined the case and observed that the manufacturing site of the products mentioned at serial No. 1 & 2 above has been changed from M/s Medtronic, Inc.710 Medtronic Parkway, Minneapolis, MN 55432, USA to M/s Medtronic Mexico S.de R.L.de CV, Av, Paseo Cucapah 10510 EI Lago, C.P. 22210 Tijuana, Baja California, Mexico and for serial No.3-6 the manufacturing site has been changed from M/s Medtronic, Inc.710 Medtronic Parkway, Minneapolis, MN 55432, USA to M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland. The firm had applied for the change of manufacturing site on 02-08-2012 but official approval from Registration Board has not been granted till date. In view of the above, clarification need to be seeked from the firm for importation of above mentioned stents and catheters since 2012**.

**Item No.XI** **Issuance of Registration Approval of "Karmi Blood Bags (Single, Double & Triple)**

 M/s IBL HealthCare, Karachi have stated that their product namely "Karmi Blood Bags (Single, Double & Triple)" submitted to R-I Section on 17th March, 2014 and was approved in 259th meeting of Registration Board. Inspection of manufacturer abroad M/s Kawasumi Laboratories (Thailand) was carried out by panel of inspectors of DRAP on 24th & 25th April, 2017. After recommendation by inspection panel, the product was forwarded to Drug Pricing Committee for price fixation but Committee referred the case to MD&MC Division due to SRO.167(I)/2017 dated 15th March, 2017 declare blood bags as medical devices. Since they have completed all steps of registration therefore, they requested the DRAP to consider their dossier application and grant them registration approval.

**Decision: After detailed deliberation and discussion, the MDB decided to issue provisional acknowledgement for registration application of the medical device namely "Karmi Blood Bags" manufactured by M/s Kawasumi Laboratories (Thailand) subject to grant of provisional establishment certificate or Establishment Licence after enforcement of new Medical Devices Rules.**

**Item No.XII**. **Request for Additional size of Synergy Monorail Everolimus Eluting**

 **Platinum Chromium Coronary Stent System (Reg. No.083389)**

 M/s Ferozsons Laboratories Limited, Nowshera was granted the registration of Synergy Monorail Everolimus Eluting Platinum Chromium Coronary Stent System with sizes as mentioned below by Drug Registration Board in its 266th meetings held on 6th & 7th February, 2017. Now the firm has requested for grant of additional size as mentioned below of the said medical device:-

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Regn.No** | **Name of Product** | **Existing Approved Sizes** | **Demanded Additional Sizes** | **Name of Manufacturer** |
| 083389 | Synergy Monorail Everolimus Eluting Platinum Chromium Coronary Stent System |

|  |  |
| --- | --- |
| Dia(mm) | Length (mm) |
| 2.25, 2.50, 2.75, 3.00,3.50, 4.00 | 8 |
| 2.25, 2.50, 2.75, 3.00,3.50, 4.00 | 12 |
| 2.25, 2.50, 2.75, 3.00,3.50, 4.00 | 16 |
| 2.25, 2.50, 2.75, 3.00,3.50, 4.00 | 20 |
| 2.25, 2.50, 2.75, 3.00,3.50, 4.00 | 24 |
| 2.25, 2.50, 2.75, 3.00,3.50, 4.00 | 28 |
| 2.25, 2.50, 2.75, 3.00,3.50, 4.00 | 32 |
| 2.25, 2.50, 2.75, 3.00,3.50, 4.00 | 38 |

 | Dia: 2.50 mm, 2.75 mm, 3.00 mm, 3.50 mm, 4.00 mmLength: 48 mm | **Legal Manufacturer**: M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlbnorough, Massachusetts 01752, USA.**Manufacturing Site**: M/s. Boston Scientific Ltd, Ballybrit Business Park, Galway, Ireland. |

 Original Free Sale Certificate from Ireland for the said product mentioning size of 48 mm length with 2.50, 2.75, 3.00, 3.50 and 4.00 mm diameter has already been submitted by the firm and the firm has again submitted copy of the same. The firm has also submitted Fee challan of Rs. 5,000/-

 The firm has also submitted application on Form-2 as per SRO 167(I)/2017 for Provisional Registration of Synergy Monorail Everolimus Eluting Platinum Chromium Coronary Stent System and fee of Rs. 20,000/-.

 It is submitted that applicant was issued Provisional Establishment Certificate on 06-04-2017 for a period of six months as per SRO 167(I)/2017.

 **Decision: After detailed deliberation and discussion, the MDB approved the following additional sizes of already registered medical devices namely, "Synergy Monorail Everolimus Eluting Platinum Chromium Coronary Stent System" having registration number 083389:**

|  |  |  |
| --- | --- | --- |
| **Name of Product** | **Approved Additional Sizes**  | **Name of Manufacturer** |
| **Synergy Monorail Everolimus Eluting Platinum Chromium Coronary Stent System** | **Length: 48 mm Diameter :** **2.50 mm,****2.75 mm,** **3.00 mm,** **3.50 mm,****4.00 mm** | **Legal Manufacturer: M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlbnorough, Massachusetts 01752, USA.****Manufacturing Site: M/s. Boston Scientific Ltd, Ballybrit Business Park, Galway, Ireland.** |

 The meeting ended with vote of thanks to and from the chair.

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