**Government of Pakistan**

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

**Drug Regulatory Authority of Pakistan**

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**MINUTES OF THE 8TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**HELD ON 13TH FEBRUARY, 2018**

8th 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 13th February, 2018. The meeting was chaired by Dr. Sheikh Akhter Hussain, Director Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan and 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 |
|  | Syed Walayat Shah,  Chief Drug Inspector,  Health Department, Khyber Pakhtunkhwa. | Ex-Officio Member |
|  | Brig.(R) Dr. WaqarAzim Niaz,  Consultant Urologist & Transplant Surgeon, Quaid-e-Azam International Hospital, Golra Mor, Islamabad. | Member |
|  | Prof. Dr. Sajid Bashir,  Prof. of Pharmaceutics, Dean Department of Pharmacy, University of Sargodha, Sargodha | Member |
|  | Dr. Abdul Haleem Khan,  Associate Professor & Chairperson, Department of Pharmacy, Forman Christian College, Lahore. | Member |
|  | Miss. Tazeen S. Bukhari,  TRF Technical Consultant for Medical Devices, Technical Resource Facility, 16-BB, Defence Housing Authority, Phase-IV, Lahore. | Member |
|  | Mr. Muhammad Asghar,  CEO, Cyber Soft Technologies,  Lahore. | Member |
|  | Dr. Mohammad Farid Khan,  Director Emergency Services,  District Kasur. | Member |
|  | Prof. Dr. SaqibShafi Sheikh,  Interventional Cardiologist/Cardiovascular Surgeon, Mayo Hospital, Lahore. | Member |
|  | Mr. Muhammad Tahir Aziz,  Chief Operating Officer, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar. | Member |
|  | Dr. Ejaz Hassan Khan,  Professor of Pathology, Prof. /Dean, North west School of Medicine, Peshawar. | Member |
|  | Dr. Ghazanfar Ali Khan,  Additional Director (MD&MC), DRAP,  Islamabad. | Secretary |

Mr. Shaikh Shakeel and Mr. Tariq Mahmood were also present on behalf of HDAP and Pakistan Medical Devices Manufacturers Association respectively as observers.

The meeting started with the recitation of the Holy Quran. The Chairman MD&MC iin his opening remarks welcomed all the participants and extended warm welcome. He informed the members that membership is a great honor entrusted to them due to their expertise in the subject of medical devices and he had great expectations from them. Thereafter members were requested to introduce themselves before formal consideration of the agenda items. After introduction of worthy members, Secretary MD&MC presented the agenda of the meeting.

**ITEM NO.I**. **INTRODUCTION, BRIEF REGARDING MEDICAL DEVICES DIVISION RESPONSIBILITIES AND MEDICAL DEVICES RULES, 2017.**

The Secretary MDB briefed the Board regarding regulation of the subject of medical devices under the Drug Regulatory Authority of Pakistan Act, 2012 as follow:-

The Drug Regulatory Authority of Pakistan Act, 2012 was promulgated on 13th November, 2012 by the Parliament for the establishment of Drug Regulatory Authority of Pakistan to regulate the manufacture, import, export, storage, distribution and sale of therapeutic goods including drugs, alternative medicines, medical devices, biologicals and other related products as may be notified by the Authority. The medical devices were thus brought under regulation. For this purpose Medical Devices Rules, 2015 were notified on 9th March, 2015 with phase-wise regulation over a span of 1 to 2 years for four risk classes (A,B,C& D). The dates were extended twice until 30th September 2016 for Class D and 8th December, 2016 for Class C medical devices.

Under these rules, Medical Device Board was constituted on 30-10-2015 which is responsible for licensing and registration of medical devices. So far 7 meetings of the Medical Device Board have been convened. A vast field of medical devices has come under regulatory ambit and as regulation of all medical devices is being done for the first time; therefore, difficulties arose in implementation of new regulations. These rules could not be 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 (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 + subject, there was no CAB registered with DRAP in last 02 years which halted the regulation process. Therefore it required to revisit and revise the Medical Devices Rules for removing practical difficulties.

Thereafter, in the recent stent issue, on the FIA report on illegal sale and usage of unregistered stents, the Honorable Supreme Court of Pakistan has taken ***suomoto*** 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; 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 cardiovascular stents. The salient features of the said SRO were as under:-

* The said SRO had a Schedule “A” of 134 lifesaving medical devices including cardiovascular 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.
* 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 were 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”, were 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.

Under SRO. 167(I)/2017, the exemption period of medical devices not included in the Schedule “A”, was further extended for 2 months.

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 Medical Devices Rules, 2017 (MDR, 2017). After completion of all legal formalities including vetting by Law & Justice Division, MDR, 2017 were approved by the Federal Government and notified on 16-01-2017. All medical devices shall now be regulated according to these new rules.

In order to facilitate the process and ensure quality and transparency, DRAP has also launched and activated the first IT based National Registry for cardiac stents. It is compulsory to enter the data of manufacturing / importation and utilization of cardiac stents in National Registry.

Federal Government has also issued a Directive to the Policy Board and DRAP to check irrational, restrictive and exorbitant prices and huge profiteering. Accordingly, the DRAP issued an advisory on 22nd March, 2017 to the Provincial Governments and all concerned for taking measures to check the irrational, restrictive, exorbitant prices and huge profiteering in cardiac stents**.**

**SALIENT FEATURES OF THE MDR, 2017:**

* All medical devices shall now be regulated according to these new rules.
* Licensing system for establishments including manufacturers and importers.
* Classification of medical devices and in vitro diagnostic medical devices into Class A, B, C and D, depending upon the level of risk they pose to patients, users and other persons, where class D represents the highest risk class.
* Methods/Rules of classification of medical devices on the basis of intended purpose, mechanism of action, duration of use etc.
* Grouping procedure/methods for medical devices into single; system; *in vitro* test kit etc.
* Procedure for registration of medical devices keeping in view the classification and grouping systems.
* Procedure for import of medical devices, components and raw materials for commercial, personal and investigational purposes.
* Procedure at custom port for clearance of medical devices, components and raw materials.
* Procedure for export of medical devices for commercial, personal and investigational purposes.
* Labeling requirements for general and in vitro diagnostic medical devices.
* Responsibilities and obligations of licensees and registration holders.
* Post market surveillance and vigilance system.
* Medical Device Board for licensing of establishments, registration of medical devices and issuance of permits for import and export of medical devices.
* Maintenance of the Medical Device Register of Pakistan, containing information of all the registered medical devices, licensed establishments and CABs.
* Fee structure of all the procedures performed by MDB or on its behalf.
* Outsourcing of the manufacturing of medical devices, processes or testing of the medical devices.
* Procedure for advertisement of medical devices.
* Medical devices rules shall be implemented phase wise to ensure availability of medical devices and ample time be given to the importers for preparation and submission of documents as per prescribed procedure. The medical devices establishments and medical devices enlistment /registration shall be exempted from operation of these rules from their commencement for a period as specified below, namely:-

|  |  |  |
| --- | --- | --- |
| **S.**  **No.** | **Establishment and class of medical devices** | **Exemption**  **period** |
|  | Import and manufacturing establishments | 6 months |
|  | Class D medical devices | 9 months. |
|  | Class C medical devices | 12 months. |
|  | Class B medical devices | 18 months. |
|  | Class A medical devices | 24 months. |

* 134 life saving or life sustaining medical devices previously included in the SRO.167 (I) / 2017 has been included in Schedule-D of the new Medical Devices Rules, 2017 and are not exempted; a provisional system for their regulation has been provided in the rules. Their importers shall obtain Provisional Establishment Certificate and Provisional Registration of their respective medical devices.
* Schedule D medical devices shall only be imported from reference countriesmentioned in rule 67 of Medical Devices Rules, 2017 or CE-Mark or Pre-qualified by WHO after submitting an application on simplified forms provided in Medical Devices Rules, 2017. Reference countries include USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland and United Kingdom.
* Role of Conformity Assessment Bodies (CABs) has now been entrusted to Medical Device Board (MDB) consisting of various experts such as cardiovascular surgeon or interventional cardiologist, urologists, nephrologists, biomedical engineer, radiologist, software or electromechanical engineer, general or orthopedic surgeon, pathologist or medical technologist, pharmacists having background in manufacturing, quality control and hospital pharmacy. Any other expert of any specialty can also be co-opted.
* Drug Sale Licence issued by the Provincial Governments shall be required by the importers of medical devices to ensure proper storage and sale.
* More options for hiring of technical staff by the importers/manufacturers have been provided in the rules.
* Class A medical devices shall be enlisted while Class B, C and D medical devices shall be registered.
* Fee for enlistment and registration of medical devices has been reduced.

**Decision:** The MDB noted the information and asked to send these rules to all members of the MDB through email.

**ITEM NO.II.** **STATEMENT OF COMMITMENT.**

Following is the proposed resolution:-

“All the members of the MDB shall strive hard for fulfillment of the responsibilities enshrined with full zeal and zest by utilizing their professional skills with honesty and integrity for the betterment of public at large. It is also resolved that the establishments will be guided in terms of up-gradation in quality in the subject field so that safe and effective medical devices are provided to patients. Nomination by the Authority as members of the MDB is a great honour along-with responsibility and the members assure that they will not be involved in any activity which comes under the definition of **conflict of interest**. The members further resolved that the decisions of the MDB shall be kept confidential till finalization and approval of minutes of the meeting of MDB”.

**Decision:** The Medical Device Board (MDB) unanimously passed the above resolution.

**Item No.III. REGULATION OF SALE OF MEDICAL DEVICES.**

Under Section 6 of the Drugs Act, 1976, sale of drugs is regulated by Provincial Governments. Accordingly, the sale of medical devices would be regulated by Provincial Governments in the prescribed manner and may for that purpose make such orders, and issue such directions to the importers, manufacturers, stockiest, retailers or other dealers of medical devices, as they may deem fit. Under Section 7(a) and (f) of the DRAP Act, 2012, the powers and functions Authority are to advise the Provincial Governments for laws that are applicable to the Provinces and to provide policy guidance to the Provincial Governments in the performance of their functions with a purpose to bring uniformity.

Medical Devices Rules, 2017 deals mainly with licensing, registration, manufacturing, import of medical devices. It is therefore proposed that Provincial Governments may be advised to formulate and implement rules regarding sale of medical devices.

**Decision:** During discussion Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist opined that the Board may guide the Provincial Governments regarding sale of medical devices including cardiac stents and that cardiac stents should be supplied directly to Cath Labs and not be kept in pharmacies. The MDB discussed the matter in detail and it was decided that Provincial Governments may be advised to formulate rules for sale of medical devices, either by changing the title of the Drug Sale Licence or introduce a separate sale licence for medical devices, but before that, the Board shall formulate guidelines for regulation of sale of medical device. The guidelines shall then be sent to the Provincial Governments. For this purpose, the Boardconstituted following committeewhich shall formulate guidelines to be sent to Provincial Governments:

1. Secretary, MDB
2. Dr. Abdul Haleem Khan, Member MDB.
3. Prof. Dr. Saqib Shafi Sheikh, Member MDB.
4. Mr. Muhammad Tahir Aziz, Member MDB.

**Item No. IV. FATE OF APPLICATIONS FOR REGISTRATION OF MEDICAL DEVICES DECLARED AS DRUG AND APPLIED UNDER DRUGS ACT, 1976.**

Before issuance of SRO. 167(I)/2017 on 15th March, 2017 medical devices like disposable syringe, infusion set, blood transfusion sets, cannula, catheter, stent, butterfly needle and auto-disable syringe were declared as drug vide different SROs and were being regulated under the Drug Act, 1976. The said SROs are now repealed and all earlier medical devices declared as drugs shall now be regulated as medical devices under Medical Devices Rules, 2017. The firms prior to repeal of medical devices declared as drugs applied on Form 5-A under Drugs (Licensing, Registering & Advertising) Rules, 1976, which were under process/pending.

All such applications either in Medical Devices Division (MDD) or in Pharmaceutical Evaluation & Registration Division beevaluated in MDD after acceptance of application on relevant forms prescribed in Medical Devices Rules, 2017.

**Decision:** The Board decided that all underprocess/pending applications of medical devices applied as drugs under Drugs(L,R,A) Rules, 1976 shall be processed under Medical Devices Rules, 2017 subject to fulfillment of requirements under Medical Devices Rules, 2017 including Establishment Licence and prescribed registration application form under these rules. Any fee submitted earlier shall be considered as medical device registration application fee, however, in case of deficient fee, the firm has to submit differential fee as prescribed under Medical Devices Rules, 2017.

**Item No. V.** **MEDICAL DEVICES ALREADY REGISTERED AS DRUGS**

It is submitted that erstwhile Ministry of Health, keeping in view the risks posed to the patients and in exercise of the powers conferred by sub clause (vi) of the clause (g) of section 3 of the Drugs Act, 1976, declared some medical devices to be drugs for the purpose of said Act**.** These devices includes disposable syringes, disposable sets for collection or transfusion of blood or giving any infusion, cannula, catheter, stent, auto-disable syringes and butterfly needles. Since then many devices have been registered as drug under the Drugs Act, 1976 and rules thereunder.

The matter was taken up in the 5th meeting of the MDB and the decision is reproduced as below:-

*"For those Schedule "A" medical devices already registered as drug, having valid registration, originating from reference countries mentioned in the SRO.167(I)/2017 and having Provisional Establishment Certificate shall be treated as registered medical device under the Medical Devices Rules, 2015. A list in this regard shall be issued by the MDMC Division."*

The matter alongwith the list of medical devices already registered as drug, having valid registration, originating from reference countries mentioned in SRO. 167(I)/2017 was placed before the MDB and the decision is reproduced as below:-

*"The Board thoroughly reviewed and discussed Medical Devices mentioned in Annex-I. As these Medical Devices are fulfilling the criteria prescribed in the SRO, therefore, the Board approved these devices as registered medical devices under Medical Devices Rules, 2015 and accordingly a list of these medical devices shall be issued by the MDMC Division. New registration numbers shall be allotted to these registered devices".*

The list was not issued since the new Rules were being framed and it was discussed with the Director/Chairman MDB that registration letters with new registration number from Medical Devices Division shall be issued for each individual medical device.

The matter is placed alongwith the list of medical devices**(Annexure-I)** being imported from reference countries or CE marked for the consideration of MDB.

**Decision:** The MDB decided that the medical devices, previously declared as drug and registered as drug under the drugs Act, 1976 and rules thereunder shall be deemed to be registered as medical device under Medical Devices Rules, 2017 till their registration is valid subject to Establishment Licence under new rules. Thereafter, at the time of renewal of registration, the firms shall apply on prescribed forms under the Medical Devices Rules, 2017 and accordingly fresh registration number shall be allotted.

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

Under rule 59 (13), the Secretary of the MDB or any officer of the MD&MC Division nominated by the MDB may perform any specific function of the MDB including the disposal of its day to day business. For this purpose, it is proposed that the power of constituting panel of inspectors/experts for local and foreign inspections of Manufacturing units for Grant of Establishment Licence(s), Renewal of Establishment License(s), Medical Device Registration, renewal of registration and routine GMP/GDP inspections, may be delegated to Director (MDMC)/Chairman MDB for smooth and efficient working of the Division.

The Board has already delegated the powers to Director (MDMC) to perform above functions in the 7th meeting of the MDB.

**Decision:** The Board delegated the above powers to Director (MDMC)/Chairman MDB for smooth and efficient working of the Division.

**Item No. VII**. **DELEGATION OF POWERS REGARDING IMPORT & EXPORT OF MEDICAL DEVICES.**

It is submitted that as per rule24 (c) (i) of Medical Device Rules, 2017states as under:

*"****MDB or any officer,authorized by it in this behalf*** *on an application being made to it prior to the import and being satisfied that the medical device is for bonafide personal use, has granted permission for the import of the said medical device"*

Rule 24 (d) of Medical Device Rules, 2017states as under:-

(a) *any medical device, the import of which is otherwise prohibited on account of non-enlistment or non-registration, may be imported for patients in hospital (public or private) subject to prior approval of* ***MDB or any officer authorized by it in this behalf*** *as per following conditions, namely:-*

*(i) the medical device shall not be sold or distributed in the market;*

*(ii) the medical device shall be on free sale in the country of origin;*

*(iii)the medical device shall be used in the hospital or institution only and not for the purpose of clinical trial, examination, test or analysis;*

*(iv)clearance certificate must be obtained from assistant director, or officer authorized, of the Authority, at the time of arrival of shipment, before customsclearance. Consumption or utilization record must be maintained by the importer, under the supervision of qualified technical staff as specified in these rules;and*

*(v) the medical device is not enlisted or registered or available in Pakistan.*

Rule 27 (1) of Medical Device Rules, 2017states as under:-

*" No establishment shall export any medical device without approval of* ***MDB or an officer authorized by it in this behalf****".*

Rule 29 (1) of Medical Device Rules, 2017states as under:-

*"An application for a permit to export small quantity of medical devices, including those the export of which is otherwise without enlistment or registration prohibited under the DRAP Act and the rules made thereunder, for the purpose of clinical investigation, examination, test or analysis shall be made to the* ***MDB or an officer authorized in this behalf*** *on the format as set out in Form-14 alongwith fee as specified in rule 63".*

Rule 34 of Medical Device Rules, 2017states as under:-

***"Export of medical devices for personal use,—*** *Small quantities of medical devices, including those the export of which is otherwise prohibited without enlistment or registration under the DRAP Act and these rules, may be exported for personal use subject to the following conditions, namely:****—***

1. *the medical device shall form part of the passenger's bonafide baggage and shall be intended for his exclusive personal use; and*
2. *the quantity of any medical device so exported shall be restricted to meet personal requirement only:-*

*Provided that any medical device exported for personal use but not forming part of bonafide personal baggage may be allowed to be exported subject to the following conditions, namely:****—***

* 1. ***the MDB or any officer authorized by it in this behalf****, on an application being made to it prior to the export and being satisfied that the medical device is form bonafide personal use, has granted permission for the export of the said medical device; and*
  2. *the quantity to be exported is, in the opinion of the MDB, reasonable and restricted to meet personal requirement only.*

The Board delegated the powers for issuance of import permits and clearance certificate for import of medical devices or any component thereof or any raw material under Medical Devices Rules, 2015 to area Assistant Directors of each province to be exercised through office Incharge /Additional Director of field offices of DRAP.

Submitted for deliberation and consideration of MDB for authorization on its behalf in aforesaid cases.

**Decision:** The Board delegated the powers for performance of above functions under the relevant rules to Additional Directors of DRAP’s field offices.

**Item No.VIII**. **CONCURRENCE OF MDB REGARDING PEC AND PROVISIONAL REGISTRATION OF MEDICAL DEVICES PROVIDED IN SCHEDULE-D OF MDR, 2017.**

Rule 52 of Medical Devices Rules, 2017 is reproduced below:-

***"Exemption from operation of the rules,—*** *(1)The medical devices’ establishments and medical devices specified in column (2) of the Table below shall, in terms of section 36 of the Act and from commencement of these rules, be exempt from operation of these rules for a period as specified in column (3) thereof, namely:* ***—***

*TABLE*

|  |  |  |
| --- | --- | --- |
| ***S.No.*** | ***Establishment and class of medical devices*** | ***Exemption period*** |
| *(1)* | *(2)* | *(3)* |
| *1.* | *Import and manufacturing establishments* | *6 months* |
| *2.* | *Class D medical devices* | *9 months.* |
| *3.* | *Class C medical devices* | *12 months.* |
| *4.* | *Class B medical devices* | *18 months.* |
| *5.* | *Class A medical devices* | *24 months.* |

*(2) Notwithstanding the exemptions contained in sub-rule (1), all life saving or life sustaining medical devices specified in Schedule-D required to be registered under these rules shall be deemed to have been registered under these rules till validity of their respective exemption period specified in sub-rule (1), subject to the condition that the establishment concerned shall, on the format set out in Form-19, make application to the MDB along with original valid agency agreement from medical-device-market-authorization-holder and such other documents specified in that form for grant of provisional establishment certificate.*

*(3) On receipt of the application and documents received under sub-rule(2), the Chairman of the MDB shall decide application within seven working days for grant of provisional establishment certificate on the format as set out in Form-20 to be signed by the secretary of the MDB which shall be valid till the date of respective validity of exemption period specified in sub-rule (1) but* ***subject to concurrence of the MDB****.*

*(4) Where the MDB concurs to the provisional establishment certificate issued under sub-rule (3), the provisional-establishment-certificate-holder shall make, on the format set out in Form-21 along with free sale certificate and supported by such documents specified in that form, application to the MDB for the grant of provisional enlistment or registration of medical device to be manufactured in Pakistan in the manufacturing facility as approved by the MDB and where the medical device is to be imported such import shall be subject to the condition that such medical device stands approved for use and sale by the regulatory authorities of the reference countries specified in rule 67 or CE marked by manufacturer whose conformity assessment is performed by conformity assessment bodies notified in NANDO database under the relevant European directive for medical devices subject to evidence and supporting documents.*

*(5) No life saving or life sustaining medical devices specified in Schedule-D shall be imported, sold and used in Pakistan unless such medical devices are imported from the sources specified in sub-rule (4).*

*(6) On receipt of the application and documents received under sub-rule (4), the Chairman of the MDB shall decide application for grant of provisional enlistment or registration certificate of the medical device on the format as set out in Form-22 to be signed by the secretary of the MDB which shall be valid till the date of respective validity of exemption periods specified in sub-rule (1) but* ***subject to concurrence of the MDB.***

*(7) Where the MDB does not concur to the provisional establishment certificate or as the case may be provisional enlistment or registration certificate of medical device and decides either to suspend or cancel such certificate, the MDB shall inform the establishment in writing of its decision after providing to the establishment an opportunity of being heard.*

*(8) The provisional establishment certificate and the provisional enlistment or registration certificate of the medical device under this rule shall further be subject to the conditions provided for in the respective Forms of such provisional certificates.*

*(9) Where the MDB, on the basis of information received or an inquiry conducted by it, is of opinion that—*

1. *the provisional establishment certificate or provisional enlistment or registration certificate of the medical device was procured by fraud or misrepresentation; or*
2. *the circumstances in which such provisional certificate was issued no longer exist; or*
3. *it is necessary in the public interest so to do,theMDB may, after affording to such provisional-certificate-holder an opportunity of being heard against the action proposed to be taken, cancel or suspend the provisional certificate or specify any further conditions to which the provisional certificate shall be subject to and inform such provisional-certificate-holder accordingly.*

*(10) The provisions of, and certificates issued under, sub-rules (2) to (9) shall remain in force till validity of respective exemption periods specified in sub-rule (1)."*

It is further submitted that case regarding permission for approval for issuance of PEC and Provisional Registration of Schedule-D medical devices and case regarding fee for applications of PEC and Provisional Registration was placed before the Authority in its 56th meeting held on 02-02-2018. The Authority decided that Division shall start working under newly promulgated SRO. Fee for any other activity having commercial significance is Rs.5000/- as per Schedule-C.

In the light of aforesaid rule, concurrence of the MDB shall be required for issuance PEC and provisional registrations for Schedule-D medical devices.

**Decision:** The MDB gave its concurrence for issuance of PEC and provisional registrations for Schedule-D medical devices. However, the list of issued PEC and provisional registrations shall be placed before the Board in next meeting for its information.

**Item No. IX**. **PERSONNAL HEARING OF M/S OTSUKA PAKISTAN LIMITED, KARACHI REGARDING DEREGISTRATION OF ITS STENTS.**

M/s Otsuka Pakistan Ltd, Karachi has informed that they have stopped import of Firebird 2 Rapamycin Eluting Cobalt Chromium Coronary Stent System (Registration No.074670) and Mustang Stent Stainless Steel Coronary Stent System (Registration No.074669) already registered in their name. Last import of Firebird-2 was made on 25-5-2017 whereas Mustang Stent was last imported on 07-06-2016. They informed that in future they do not intend to import these products and ultimately will discontinue these products (**Annex-II**).

Keeping in view the above, the firm has been advised to appear before the MDB for personal hearing during the meeting.

**Decision:** Dr Arshad Kamal, Senior Manager QA/ Manager Regulatory Affairs appeared before the Board and informed the Board to de-register Firebird 2 Rapamycin Eluting Cobalt Chromium Coronary Stent System (Registration No.074670) and Mustang Stent Stainless Steel Coronary Stent System (Registration No.074669) already registered in their name due to afore mentioned reasons. The Board asked the Firm representative regarding existing stock of both stents. In reply, the representative informed that there is no stock of Mustang Stent, however, 80 stents of Firebird 2 are present in the market.

The Board de-registered Firebird 2 Rapamycin Eluting Cobalt Chromium Coronary Stent System (Registration No.074670) and Mustang Stent Stainless Steel Coronary Stent System (Registration No.074669) on the request of the firm due to afore mentioned reasons. Furthermore, the Board directed the Firm to re-call all existing stock of Firebird 2 stent immediately and dispose it off under the DRAP Act, 2012 and rules framed thereunder in coordination with Additional Director (E&M), Karachi and area FID.

**Item No. X**. **MEDICAL DEVICES ADVERSE EVENT REPORTING FORM.**

Rule 49(1) of MDR, 2017 is reproduced as below:-

For the purpose of post-marketing surveillance and vigilance of marketed medical devices, a licensee shall establish, maintain and implement an appropriate and effective post-marketing surveillance and vigilance system of medical devices he is dealing with which shall also include the following elements, namely: **—**

1. distribution records;
2. complaint handling system;
3. mandatory problem reporting, including investigation of problem or incident;
4. field corrective action; and
5. recall procedure.

Medical Device Adverse Event Reporting Form was approved by the MDB in its 3rd meeting according to MDR, 2015. However, in 7th meeting of the MDB it was emphasized that feedback may be taken from institutions using locally manufactured medical devices regarding their safety and performance. The Board decided as under:-

*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.*

According to Board decision, a new Medical Device Adverse Event Reporting Form according to Medical Devices Rules, 2017 has been designed and placed at **Annexure-II**I.

**Decision:** The Board discussed the matter at length and appreciated the efforts so far made by the worthy member and directed that Medical Device Adverse Event Reporting Form may be shared with other Board members and observers for their comments and finalize the form with endorsement by Mr. Muhammad Tahir Aziz.

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

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**ANNEX-I**

**LIST OF MEDICAL DEVICES DEEMED TO BE REGISTERED**

**UNDER MEDICAL DEVICES RULES, 2017**

**(AS PER INITIAL REGISTRATION LETTER)**

**CATHETERS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.No** | **Name of Firm/ Importer.** | **Name of Manufacturer** | **Reg.No.** | **Name of Medical Device** | **Date of**  **Registration** |
|  | M/s Iqbal& Company,  Islamabad. | M/s. Arrow International, Inc (subsidiary of Teleflex, Incorporated) 2400 Bernville Road, Reading PA 19605, USA) | 074635 | Arrow Central Venous Catheterization Set. | 21-2-2013 |
|  | -do- | -do- | 074636 | Arrow Intra Aortic Balloon Catheters. | 21-2-2013 |
|  | -do- | -do- | 074637 | Arrow Two Lumen Haemodialysis Catheterization Set. | 21-2-2013 |
|  | -do- | -do- | 074638 | Arrow Balloon Wedge Pressure Catheters | 21-2-2013 |
|  | -do- | -do- | 074639 | Arrow Arterial Catheterization Set. | 21-2-2013 |
|  | -do- | -do- | 074640 | Arrow Berman Angiographic Balloon Catheters. | 21-2-2013 |
|  | -do- | -do- | 074641 | Arrow Multi Lumen Access Catheters. | 21-2-2013 |
|  | M/s Digital Imaging Systems, Lahore. | Responsible Manufacturer: M/s. Abbott Vascular Lakeside Drive, California, USA.  Manufacturing Site: M/s. Abbott Vascular Cashel Road, Clonmel, County Tipperary, Ireland). | 074648 | Trek RX Coronary Dilatation Catheter | 12-4-2013 |
|  | -do- | -do- | 074649 | Mini Trek RX Coronary Dilatation Catheter | -do- |
|  | -do- | -do- | 074650 | NC Trek RX Coronary Dilatation Catheter. | -do- |
|  | M/s Intek Corporation, Rawalpindi | M/s. OrbusNeich Medical B.V. Drs, W. Van Royenstraat, ANHoevelaken, The Netherlands. | 074673 | Scoreflex Coronary Dilatation Catheter. | 1-1-2014 |
|  | -do- | -do- | 074674 | Sapphire NC Coronary Dilatation Catheter | 1-1-2014 |
|  | -do- | -do- | 074675 | “Sapphire II (Rx)” Coronary Dilatation Catheter | 1-1-2014 |
|  | -do- | -do- | 074677 | Sapphire Coronary Dilatation Catheter | 1-1-2014 |
|  | M/s Cor-Med, Rawalpindi. | M/s. IHT, Iberhospitex S.A, Barcelona, Spain) | 074689 | Fairway Rapid Exchange Dilatation Catheter for PTCA | 25-4-2014 |
|  | M/s. B.Braun Pakistan (Pvt) Ltd., Karachi. | Legal Manufacturer: M/s. PendraCare International B.V., Van der Waalspark- 22, VC Leek, Netherland.  Marketing Authorization Holder & Central Distributors: M/s. B.BraunMelsungen AG, Vascular System, Sieversufer 8, D-12359, Berlin, Germany). | 080168 | Angiodyn” Angiographic Catheter. | 10-02-2016 |
|  | -do- | Legal Manufacturer: M/s. B.BraunMelsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen, Germany.  Manufacturing Site: B. Braun Melsungen AG, Vascular Systems, Sieversufer 8, 12359 Berlin, Germany. | 080169 | SeQuent Neo Rapid Exchange Coronary (PTCA) Balloon Catheter. | 10-02-2016 |
|  | M/s Healthtec, Rawalpindi. | (Manufacturer: Blue Medical Device B.V, Steenovemweg 19, 5708 NH Helmond, The Netherlands.  Production plant: Panovenweg 7, 5708 HR Helmond, The Netherlands). | 080409 | Force NC Balloon Dilatation Catheter | 08-03-2016 |
|  | -do- | -do- | 080410 | Everest SC Balloon Dilatation Catheter | 08-03-2016 |
|  | -do- | -do- | 080411 | Summit CTO Balloon Dilation Catheter | 08-03-2016 |
|  | M/s Healthtec, Rawalpindi. | **Manufacturer:** Blue Medical Device B.V, Steenovemweg 19, 5708 NH Helmond, The Netherlands  **Production plant:** Panovenweg 7, 5708 HR Helmond, The Netherlands). | 082017 | Protégé DEB Dilatation Catheter  (Paclitaxel Eluting Balloon Dilatation Catheter) | 30-9-2016 |
|  | M/s Intek,  Rawalpindi. | **Legal Manufacturer:** M/s Terumo Corporation-1,2-chome, Hatagaya, Shibuya-ku, Tokyo, Japan.  **Manufacturing Site:** M/s Ashitaka Factory of Terumo Corporation, 150, Maimaigi-cho, Fujinomiya city, Shizuoka Prefecture, Japan. | 083119 | Progreat  (Micro Catheter System) | 09-02-2017 |
|  | -do- | **-do-** | 083120 | Heartrail II PTCA Guiding Catheter. | 09-02-2017 |
|  | -do- | **Manufactured by:** M/s OrbusNeich Medical B.V. Drs. W.VanRoyenstraat 5, 3871 AN Hoevelaken, The Netherlands. | 083121 | Sapphire II NC Coronary Dilatation Catheter | 09-02-2017 |
|  | -do- | **-do-** | 083122 | Sapphire II PRO Coronary Dilatation Catheter | 09-02-2017 |
|  | M/s Healthtec,  Rawalpindi. | **Manufacturer:** M/s PendraCAre International B.V. Vander Waals Park 22, 9351 VC Leek, The Netherlands. | 083123 | Primum Hydrophilic Guiding Catheter | 07-03-2017 |
|  | M/s Intek,  Rawalpindi. | **Legal Manufacturer:**M/s Terumo Corporation, 44-1,2-chome, Hatagaya, Shibuya-ku, Tokyo, Japan.  **Manufacturing Site:** M/s Ashitaka Factory of Terumo Corporation, 150, Maimaigi-cho, Fujinomiya city, Shizuoka Prefecture, Japan. | 083127 | RadifocusOptitorque  (Angiographic Catheter)   |  |  | | --- | --- | |  |  | |  |  | |  |  | | 06-3-2017 |
|  | -do- | -do- | 083128 | Ryujin Plus PTCA Dilatation Catheter | 06-3-2017 |
|  | M/s ACP System.  Karachi. | **Legal Manufacturer:** M/s Medtronic, Inc, 710 Medtronic Parkway N.E., Minneapolis, 55432,US.  **Manufacturing Facility:** M/s Medtronic Mexico S. de R.L. de CV, Av. PaseoCucapah, 10510 El  Lago, C.P.22210 Tijuana, Baja California, Mexico. | 083130 | Euphora Rapid Exchange Balloon Dilatation Catheter | 07-03-2017 |
|  | M/s Intek,  Rawalpindi. | Manufactured By:  M/s Lepu Medical Technology (Beijing) Co., Ltd., no 37 Chaoqian Rd, Changping district, Beijing, China.  (Free sale certificate from regulatory authority of Netherlands also provided) | 083134 | Hoper PTCA Balloon Dilatation Catheter | 06-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera.** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA. | 083135 | Emerge Over-The-Wire PTCA Dilatation Catheter | 08-03-2017 |
|  | -do- | -do- | 083136 | Emerge MONORAIL TM PTCA Dilatation Catheter | 08-03-2017 |
|  | -do- | -do- | 083137 | NC Quantum Apex TM Monorail TM PTCA Dilatation Catheter | 08-03-2017 |
|  | -do- | -do- | 083138 | Maverick 2TM Monorail TM PTCA Dilatation Catheter | 08-03-2017 |
|  | -do- | **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. | 083390 | Flextome TM Cutting Balloon TM Monorail TM Microsurgical Dilatation Device | 09-03-2017 |
|  | M/s B.Braun Pakistan (Pvt) Limited,  Karachi. | **Manufacturer:**  B.BraunMelsungenAG Carl-Braun –Stabe 1 34212 Melsungen, Germany.  **Manufacturing Site:** B.BraunMelsungen AG Vascular Systems Sieversufer 8, 12359 Berlin, Germany. | 083393 | Sequent Please Neo Paclitaxel Releasing Rapid Exchange PTCA Balloon Catheter | 10-03-2017 |
|  | M/s Hashir Surgical Services,  Peshawar. | **Manufactured By:** M/s Intra Special Catheter GmbH, Oststrasse 2, 66780 Rehlingen-Siersburg,  Germany | 083396 | Trilucath Central Venous Catheter-3 Lumen | 10-03-2017 |
|  | -do- | -do- | 083397 | Venoseld Central Venus Catheter-I Lumen. | 10-03-2017 |
|  | -do- | -do- | 083398 | Duocath Central Venus Catheter 2-Lumen. | 10-03-2017 |
|  | -do- | -do- | 083399 | Duocath Hemodialysis Catheter 2-Lumen. | 10-03-2017 |
|  | -do- | -do- | 083400 | Quadrocath Central Venus Catheter 4-Lumen | 10-03-2017 |
|  | -do- | -do- | 083401 | Trilucath Hemodialysis Catheter 3-Lumen | 10-03-2017 |
|  | M/s Digital Imaging Systems,Lahore. | **Name of Owner Operator and manufacturing Facility**:  M/s Volcano Corporation 2870 Kilgore rd, Rancho cordova, CA USA 95670 | 083407 | Eagle Eye Platinum & ST-IVUS Catheter. | 10-03-2017 |
|  | M/s ACP System.  Karachi. | **Legal Manufacturer:** M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432, USA.  **Manufacturing Site**: M/s Medtronic Vascular, 37A Cherry Hill Drive, Danvers, MA 01923, USA. | 083410 | Export Advance Aspiration Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **­­­**  **Manufacturing Site:** M/s. Boston Scientific Limited, Business and Technology Park, Model Farm Road CORK, Ireland. | 083413 | CRE Pulmonary Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083414 | Coyote TM Monorail TM PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083415 | Coyote TM ES Monorail TM PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083416 | Coyote TM Over-The-Wite PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083417 | Coyote TM ES Over-The-Wire PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083418 | Sterling TM Monorail TM PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083419 | Mustang TM Over-The-Wire PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s. Promed International,  Rawalpindi. | **Legal Manufacturer:** M/s Biosensors Interventional Technologies Pte Ltd, 36 JalanTukang, Singapore 619266, Singapore.  **Manufacturing Site:** M/s Biosensors Interventional Technologies Pte Ltd, 36 JalanTukang, Singapore 619266, Singapore.  (Free sale certificate from regulatory authority of Switzerland provided) | 083420 | PowerlineTM PTCA Catheter | 14-03-2017 |
|  | M/s Genus, Karachi. | **Manufactured by:** M/s Umbra Medical Products, Inc, 8930 East Roan Lane, Inverness, Florida, 34450 USA. | 083421 | Hawk TM-SC- PTCA Balloon Catheter Semi-Compliant | 15-03-2017 |
|  | -do- | **-do-** | 083422 | Falcon Guiding Catheter | 15-03-2017 |
|  | -do- | **-do-** | 083423 | Hawk TM NC- PTCA Balloon Catheter Non-Compliant | 15-03-2017 |
|  | M/s Hakimsons (Pvt) Limited, Karachi. | **Manufactured by:** M/s Life Vascular Devices Biotech, S.L., C.I.F. B-65405169, Cami de Can’Ubach, 11 (pol. IND. Les Fallulles), 08620 SANT VICENC, DELS HORTS, Barcelona, Spain. | 083430 | IvascularXperience  CateterBalon De DilatacionCoronario  (Coronary Dilatation Balloon Catheter ) | 15-03-2017 |
|  | -do- | **-do-** | 083431 | Ivascular Oceanus 35  Cateterbalon de predilatacionperifericoparaguia de alambre de 0.014 (PTA Balloon Dilatation Catheter ) | 15-03-2017 |
|  | -do- | **-do-** | 083432 | Oceanus 14 Peripheral Balloon Dilatation Catheter | 15-03-2017 |

**STENTS**

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| --- | --- | --- | --- | --- | --- |
| **S.No** | **Name of Firm/ Importer.** | **Name of Manufacturer** | **Reg.No.** | **Name of Medical Device** | **Date of**  **Registration** |
|  | M/s Digital Imaging Systems, Lahore. | Responsible Manufacturer: M/s. Abbott Vascular Lakeside Drive, California, USA.  Manufacturing Site: M/s. Abbott Vascular Cashel Road, Clonmel, County Tipperary, Ireland. | 074642 | Xience V Everolimus Eluting Coronary Stent System. | 12-4-2013 |
|  | -do- | -do- | 074643 | Xience Prime Everolimus Eluting Coronary Stent System | -do- |
|  | -do- | -do- | 074644 | Omnilink Elite Peripheral Stent System. | -do- |
|  | -do- | -do- | 074645 | Multi-Link Vision Coronary Stent System | -do- |
|  | -do- | -do- | 074646 | Multi-Link Minivision Coronary Stent System | -do- |
|  | -do- | -do- | 074647 | Multi-Link Zeta Coronary Stent System | -do- |
|  | -do- | Responsible Manufacturer and Manufacturing Site: M/s. Abbott Vascular Lakeside Drive, California, USA | 074651 | RX Acculink Carotid Stent System | -do- |
|  | -do- | -do- | 074652 | RX Herculink Elite Peripheral Stent System. | -do- |
|  | M/s Intek Corporation, Rawalpindi | M/s. OrbusNeich Medical B.V. Drs, W. Van Royenstraat, ANHoevelaken, The Netherlands. | 074676 | Genous Bioengineered Cobalt Chromium Stent Delivery System. | 1-1-2014 |
|  | -do- | -do- | 074678 | AzuleCoCr Alloy Coronary Stent Delivery System | 1-1-2014 |
|  | M/s Cor-Med, Rawalpindi. | M/s. IHT, Iberhospitex S.A, Barcelona, Spain | 074690 | Bionert Inert Coronary Stent (Bare Metal Stent) | 25-4-2014 |
|  | -do- | -do- | 074691 | Active Paclitaxel Eluting Coronary Stent | 25-4-2014 |
|  | M/s Ferozsons Laboratories Limited, Nowshera. | Legal Manufacturer : M/s. Boston Scientific Corporation, USA  Manufacturing Site :M/s Boston Scientific Ireland Ltd, Ireland. | 074716 | Promus ® Element-Plus Monorail TM  (Everolimus-Eluting Coronary Artery Stent) | 8-4-2015 |
|  | M/s Intek Corporation, Rawalpindi. | M/s. OrbusNeich Medical B.V. Drs, W. Van Royenstraat, AN Hoevelaken, The Netherland. | 080003 | Combo Bio-Engineered Sirolimus Eluting Stent.  (Combo Dual Therapy Stent) | 26-1-2016 |
|  | -do- | Legal Manufacturer: M/s Terumo Europe N.V., Interleuvenlaan 40, 3001 Leuven, Belgium.  Manufacturing Site: Ashitaka Factory of Terumo Corporation, 150, Maimaigi-cho, Fujinomiya | 080004 | Nobori Drug Eluting Stent System  (Biolimus A-9 Eluting Stent) | 26-1-2016 |
|  | -do- | Legal Manufacturer: M/s Terumo Europe N.V., Interleuvenlaan 40, 3001 Leuven, Belgium.  Manufacturing Site: Ashitaka Factory of Terumo Corporation, 150, Maimaigi-cho, Fujinomiya City, Shizuoka Prefecture 418-0015, Japan.  Design Site: Terumo Corporation, R&D Centre, 1500, Inokuchi, Nakai-Machi, Ashigarakami-gun,  Kanagawa, Perfecture, Japan. | 080005 | UltimasterSirolimus Eluting Coronary Stent System | 26-1-2016 |
|  | M/s. B.Braun Pakistan (Pvt) Ltd., Karachi. | Legal Manufacturer: M/s. B.BraunMelsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen, Germany.  Manufacturing Site: B. Braun Melsungen AG, Vascular Systems, Sieversufer 8, 12359 Berlin, Germany. | 080170 | Coroflex ISAR  (Sirolimus Eluting Polymer-Free Coronary Stent System) | 10-02-2016 |
|  | M/s Healthtec, Rawalpindi. | Manufacturer: Blue Medical Device B.V, Steenovemweg 19, 5708 NH Helmond, The Netherlands.  Production plant: Panovenweg 7, 5708 HR Helmond, The Netherlands. | 080412 | Track CoCr Coronary Stent System  (Bare Metal) | 08-03-2016 |
|  | M/s Ferozsons Laboratories Limited, Nowshera. | Owner Operator: M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA 01752, USA.  Manufacturing Site: M/s Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland | 080719 | Promus Premier TM Monorail TMEverolimus-Eluting Platinum Chromium Coronary Stent System | 10-5-2016 |
|  | M/s. Promed International,  Rawalpindi. | Legal Manufacturer :M/s Biosensor Europe SA,. Rue de Lausanne 29, 1110 Morges, Switzerland.  Manufacturing Site: Biosensor Interventional Technologies Pte Ltd, 36 JalanTukang, Singapore 619266.  Sterilization Sites: BGS Beta-Gamma-Service GmbH & Co KG. Fritz-Kotz-Strasse 16, 51674 Wiehi, Germany.  Electron Beam Sdn, Bhd, Lot 7, Jalan Sungai Pinang 4/3, Taman Perindustrian Pulau Indah (Fasa 2), 42920 Port Kalang, Selangor, Malaysia. | 081522 | BioMatrix Flex TM Drug Eluting Coronary Stent System  (Biolimus A9) | 19-8-2016 |
|  | -do- | -do- | 081523 | Biofreedom Drug Coated Coronary Stent System  (Biolimus A9) | 19-8-2016 |
|  | M/s Cardiovascular Medical System, Lahore. | **Owner/Legal Manufacturer:** M/s amg International GmbH Lohnfeld 26, D-21423 Winsen-Luhe, Germany.  **Manufactured by:** M/s QualiMed Innovative Medizinprodukte GmbH, BoschstraBe 16, 21423, Winsen- Luhe, Germany. | 082105 | ITRIX Rapamycin Eluting Coronary Stent Implantation System | 30-9-2016 |
|  | -do- | **-do-** | 082016 | ARTHOS Pico Stent Implantation System | 30-9-2016 |
|  | M/s Healthtec,  Rawalpindi. | **Manufacturer:** Blue Medical Device B.V,Steenovenweg 19, 5708 HN Helmand Netherlands  **Production plan**t: Panoverweg 7 5708 HR Helmond, Netherlands. | 082020 | Pioneer  (Cobalt Chromium Stent mounted on Paclitaxel Eluting Balloon Catheter) | 09-02-2017 |
|  | M/s. Intek Corporation,  Rawalpindi. | **Legal Manufacturer:** M/s Terumo Europe N.V. Interleuvenlaan 40, 3001 Leuven, Belgium.  **Manufacturing Site:** M/s Terumo Corporation Ashitaka Plant, 150, Maimaigi-cho, Fujinomiya city, Shizuoka Prefecture 418-0015, Japan. | 082021 | Kaname Cobalt Chromium Coronary Stent System | 09-02-2017 |
|  | M/s Digital Imaging Systems,  Lahore. | **Legal Manufacturer:** M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA.  **Manufacturing Site:** M/s Abbott Vascular, Cashel Road, Clonmel, CountyTipperary, Ireland. | 083124 | XienceXpeditionEverolimus Eluting Coronary Stent System | 06-03-2017 |
|  | M/s Digital Imaging Systems,  Lahore. | **Responsible Manufacturer:** M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA.  **Manufacturing Site:** M/s Abbott Vascular, 26531 Ynez Road, Temecula, CA 92591, USA. | 083125 | Absorb GT1 Bioresorbable Vascular Scaffold System | 06-03-2017 |
|  | M/s B.Braun Pakistan (Pvt) Limited,  Karachi/ | **Responsible Manufacturer:** M/s B.BraunMelsungen AG, Caril-Braun-StraBe 1, 34212 Melsungen, Germany.  **Manufacturing Site:** M/s B.BraunMelsungen AG Vascular System Sieversufer 8, 12359 Berlin Germany. | 083129 | Coroflex Blue Neo Coronary Stent System | 07-03-2017 |
|  | M/s ACP System.  Karachi. | **Legal Manufacturer:** M/s Medtronic, Inc, 710 Medtronic Parkway, Minneapolis, Minnesota  55432, USA.  **Manufacturing Site:** M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland. | 083131 | Resolute Onyx Zotarolimus-Eluting Coronary Stent System | 07-03-2017 |
|  | M/s Promed International,  Rawalpindi. | **Legal Manufacturer:** M/s Biosensors Europe SA, Rue De Lausanne 29, 1110 Morges,  Switzerland.  **Manufacturing Site:** M/s Biosensors Interventional Technologies Pte Ltd, 36 JalanTukang, Singapore 619266, Singapore. | 083132 | BioMatrixNeoflexTMDrug Eluting Coronary Stent System. | 07-03-2017 |
|  | M/s Intek Corp. Rawalpindi. | Manufactured By:  M/s Lepu Medical Technology (Beijing) Co., Ltd., no 37 Chaoqian Rd, Changping district, Beijing, China.  (Free sale certificate from regulatory authority of Netherlands also provided) | 083133 | Partner Sirolimus-Eluting Coronary Stent System | 06-03-2017 |
|  | M/s Ferozsons Laboratories Limited, Nowshera. | **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. | 083389 | SynergyTM Monorail TM EveroliusElutingPlatinumChromiumCoronaryStent System | 09-03-2017 |
|  | M/s B.Braun Pakistan (Pvt) Limited,  Karachi. | **Manufacturer:** B.BraunMelsungenAG Carl-Braun –Stabe 1 34212 Melsungen, Germany.  **Manufacturing Site:** B.BraunMelsungen AG Vascular Systems Sieversufer 8, 12359 Berlin, Germany. | 083394 | Coroflex ISAR NEO  Sirolimus-eluting Coronary Stent System | 10-03-2017 |
|  | M/s Promed International,  Rawalpindi. | **Legal Manufacturer:** M/s Biosnsor Europe SA, Rue De Lausanne 29, 1110 Morges, Switzerland.  **Manufacturing Site:** M/s Biosensors Interventional Technologies Pte Ltd, 36 JalanTukang, Singapore 619266, Singapore. | 083402 | BioMatrix Alpha TM Drug Eluting Coronary Stent System  (Biolimus A9) | 10-03-2017 |
|  | M/s Digital Imaging Systems, Lahore. | **Legal Manufacturer:** M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA.  **Manufacturing Site:** M/s Abbott Vascular, Cashel Road, Clonmel, CountyTipperary, Ireland. | 083404 | Xience Alpine Everolimus Eluting Coronary Stent System | 10-03-2017 |
|  | -do- | **-do-** | 083405 | Graft Master RX Coronary Stent Graft System | 10-03-2017 |
|  | M/s Digital Imaging Systems,  Lahore. | **Manufactured By:** M/s Abbott Vascular, Cashel Road, Clonmel, CountyTipperary, Ireland.  **Legal Manufacturer :**M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA. | 083406 | Multi link 8 Coronary Stent System  (Cobalt Chromium) | 10-03-2017 |
|  | M/s ACP System.  13 &23,Naval Fleet Club, Iqbal (S.J) Shaheed Road,  Karachi. | Legal Manufacturer: M/s Medtronic, Inc.710 Medtronic Parkway NE Minneapolis, MN 55432, USA.  Manufacturing Site: M/s Medtronic Ireland, Parkmore Business Park West Galway, Ireland. | 083411 | Driver Sprint Rapid Exchange Coronary Stent System | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  P.O.Ferozsons, Amangarh,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA. | 083412 | RebelTMMonorailTMPtCr Coronary Stent System | 10-03-2017 |
|  | F.W Distributors, Rawalpindi. | M/s Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark. | 083425 | Biosoft Duo Mujolti Length Hydro-Coated Urethral Stent Kit (long term) | 15-03-2017 |
|  | -do- | -do- | 083426 | Double Loop Urethral Stent in PA OR PU (Short Term) | 15-03-2017 |
|  | Hakimsons (Pvt) Limited, Karachi | **Manufactured by:** M/s Life Vascular Devices Biotech, S.L., C.I.F. B-65405169, Cami de Can’Ubach, 11 (pol. IND. Les Fallulles), 08620 SANT VICENC, DELS HORTS, Barcelona, Spain. | 083429 | IVASCULAR ARCHITECT  Sistema de Stent CoronarioCoCr (CoCr Coronary Stent System) | 15-03-2017 |
|  | M/s Genus, Karachi. | **Manufactured by:** M/s Umbra Medical Products, Inc, 8930 East Roan Lane, Inverness, Florida 34450 USA. | 083408 | Silver Stent-CC Cobalt Chromium Drug Eluting Stent | 15-03-2017 |
|  | -do- | **-do-** | 083409 | Affinity CC Cobalt Chromium Sirolimus Eluting Stent. | 15-03-2017 |

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** DRAP Adverse Event Reference No.\_\_\_\_\_\_\_**

**Drug Regulatory Authority of Pakistan**

**(MDMC-Division)**

**MEDICAL DEVICE ADVERSE EVENT REPORTING FORM**

(for use byManufacturers, Importers or Distributors)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1. PATIENT INFORMATION** | | | | | | | |
| Patient Initial | |  | | | | | |
| Gender | |  | | | | | |
| Age of patient at time of event (years) | |  | | | | | |
| Weight in Kg | |  | | | | | |
| **2. DEVICE DETAILS** | | | | | | | |
| Device Name (Brand Name) | |  | | | | | |
| Usage of Device/Intended purpose | |  | | | | | |
| DRAP Reg/ Enlist No. (Ifany) | |  | | | | | |
| Catalogue No. | |  | | | | | |
| Model No. | |  | | | | | |
| Lot/Batch No. | |  | | | | | |
| Serial No. | |  | | | | | |
| Software version( if any) | |  | | | | | |
| GMDN Term | |  | | | | | |
| Expiry Date of the Medical Device | |  | | | | | |
| * Date of implantation (if implantable Medical Device) * Is this a single use device that was reprocessed and reused on a patient? Provide detail if yes. | |  | | | | | |
|  | | | | | |
| Name &Addressof Manufacturer | |  | | | | | |
| **3. ADVERSE EVENT** | | | | | | | |
| Report Type (please select one) | | Initial Follow-up Final Trend | | | | | |
| Adverse Event Category (please select one) | | Serious Public Health Threat Death Birth defect  Serious Deterioration in State of Health Others | | | | | |
| Date of Adverse Event (AE) | |  | | | | | |
| Date on which Company was informed about AE . | |  | | | | | |
| **4. PARTICULARS OF REPORTING COMPANY/ IMPORTER / DISTRIBUTOR** | | | | | | | |
| Name of Organization | |  | | | | | |
| Company Address | |  | | | | | |
| Contact person name | |  | | | | | |
| Designation | |  | | | | | |
| Tel No. | |  | | | | | |
| Email | |  | | | | | |
| **5. DESCRIPTION OF EVENT** | | | | | | | |
| Device operator(please select one) | Physician  Patient  Others (please specify: \_\_\_\_\_\_\_\_\_\_  None or problem noted prior to use | | | | | | |
| Device disposition / current location |  | | | | | | |
| Description of event or problem (including any patient follow up as a result of the event/problem |  | | | | | | |
| Relevant lab data/ preexisting medical conditions of the patienti.e., allergies, pregnancy etc. |  | | | | | | |
| Frequency of occurrence of similar adverse events globally in the past 3 years (Number of adverse events /total number supplied by year) | **Year** | | **No of similar AEs** | **Total number supplied** | | | **Frequency of occurrence (%)** |
|  | |  |  | | |  |
| Frequency of occurrence of similar adverse events in Pakistan in the past 3 years (number of adverse events /total number supplied by year) | **Year** | | **No of similar AEs** | **Total number supplied** | | | **Frequency of occurrence (%)** |
|  | |  |  | | |  |
| No. of Patients Involved |  | | | | | | |
| No. of Devices Involved |  | | | | | | |
| **6. RESULTS OF PRODUCT OWNER’S INVESTIGATION** | | | | | | | |
| Product Owner’s device analysis result |  | | | | | | |
| Device history review |  | | | | | | |
| Course of action/ remedial/ corrective/ preventive action |  | | | | | | |
| **7. HEALTHCARE FACILITY INFORMATION** | | | | | | | |
| Name |  | | | | | | |
| Address |  | | | | | | |
| Concerned Person Name |  | | | | | | |
| Job title |  | | | | | | |
| Tel No. |  | | | | Fax No. |  | |
| Email |  | | | | | | |
| **8. OTHER INFORMATION** |  | | | | | | |

**Undertaking**:

I attest that the information submitted is true and accurate, and that I am authorized to submit this form on behalf of the company.

Name& Designation

Signature&Date

**Submitting this report by**

Mailing Address National Pharmacovigilance Center, Division of Pharmacy Services, 3rdFloor,DRAP, T.F.Complex, G-9/4, Islamabad.

**Note:** Provide a readable soft copy (Microsoft Office Word) in USB / CD.

**Guidance on how to fill this form**

The following provides some guidance on what information is required in some parts of the form.

**General information**

Each field must be completed with the requested information, “NA” if not applicable, or “unknown” when the data is not available. If the space provided in the form is insufficient, please provide the information as an attachment. You may also use the “Other Information” section at the end of the form to provide any additional details that are relevant and not requested elsewhere.

**Reference number**

* DRAP Adverse Event Reference No.: The reference number given by Drug Regulatory Authority of Pakistan during acknowledgement of the adverse event. It is used as a reference for future correspondence with Medical Device Board. This reference no would only become available after the initial report has been submitted.

**Device Details**

* DRAP registration / Enlistment No: Indicate the regulatory approval numbers that apply to all devices affected by the AE. If device has been exempted from product registration, indicate the basis for exemption, e.g. Class A Medical Device (02 years).

**Report type and Adverse Event Category**

* Initial: The first report that the reporter (dealers and registrant) is submitting about an event. The reporter is expected to submit further information about the event within 30days.
* Follow-up: Additional information to previous (initial or follow-up) report.
* Final: The last report that the reporter expects to submit about an event. The initial report can be a final report if the reporter has all the information about the event.
* Trend: Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called trend reports. Under the quality management system requirements, the manufacturer is expected to monitor trends of significant adverse events.
* Serious Threat to Public Health: Select this category when the event represents a serious threat to public. The initial report for this category of adverse events must be submitted not later than 48 hours after the reporter becomes aware of the event.
* Death/Serious Deterioration in State of Health: Select this category when the adverse event results in the death or serious deterioration in state of health of a patient, user or other person. The initial report for this category must be submitted not later than 10 days after the reporter becomes aware of the event.
* Others: Select this category when the adverse event was a near incident or is the result of testing or other analysis and event or further occurrence could lead to death or serious injury or a patient, user or other person. The initial report for this category must be submitted not later than 30 days after the reporter becoming aware of the event.
* GMDN Code and Term: Global Medical Device Nomenclature Code and explanatory term, e.g. 12345 – Stent , Bare metal.

**Description of Event**

* Device Disposition/ Current Location: Where and in what state the device is at the time of the report, e.g. destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

**Results of Product Owner’s Investigation**

* Product Owner’s Device Analysis Results: Specify, for this event, details of investigation methods, results and conclusions. The rationale for the course of action taken to investigate the incident should be included. The details of the actions to be completed and the timelines for their completion should be included. If no investigation is to be done, a rational needs to be provided here. The root cause should be identified. The root cause would ascertain the most likely reason why the problem occurred with the medical device. This may not be available at time of reporting.
* Device History Review: Includes a review of other similar events involving the same lot/batch, it should also include a review of device history records for each batch, lot or unit to ensure that the device was manufactured according to specifications, no anomalies during the manufacturing process etc.
* Course of Action / Remedial Action/ Corrective Action/ Preventive Action: Includes information on actions taken to correct the problem, including any post-market surveillance, recalls, or corrective or preventive actions and the design and manufacture of the device. This should also include the rationale for performing the corrective action. If no corrective action is to be taken, a rationale needs to be provided here. This may not be available at time of reporting.