**Government of Pakistan**

**Drug Regulatory Authority of Pakistan**

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

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**MINUTES OF THE 5TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**HELD ON 25TH MAY, 2017**

5th meeting of the Medical Device Board (MDB) was held in the committee room of TF Complex, G-9/4, Islamabad on 25th May, 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:-

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| --- | --- | --- |
| **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,  Senior 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 |
|  | Prof. Dr. Muhammad Nadeem Ahmad,  Department of Radiology, Aga Khan University Hospital, Karachi. | Member |
|  | Brig.(R) Dr. Waqar Azim Niaz, Consultant Urologist & Transplant Surgeon, Quaid-e-Azam International Hospital, Golra Mor, Islamabad. | Member |
|  | Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad. | Member |
|  | Mr. Muhammad Tahir Aziz  Chief Operating Officer,  Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar | Member |
|  | Dr. Ghazanfar Ali Khan,  Deputy Director (MDMC),  Drug Regulatory Authority of Pakistan,  Islamabad. | Member/Secretary |

The meeting started with recitation of the Holy Quran.

**Item No. I.** **CONFIRMATION OF MINUTES OF 4TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**Decision:** The Board confirmed the minutes of 4th meeting of MDB.

**Item No. II**. **UPDATE REGARDING THE PROVISIONAL ESTABLISHMENT CERTIFICATE (PEC) AND PRODUCT REGISTRATION ACKNOWLEDGEMENTS 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, **49** Provisional Establishment Certificates under this SRO have been issued to the applicant firms and **107** acknowledgements for Provisional Registration of medical devices have also been issued.

Furthermore, as provided under the SRO. 167(I)/2017, those medical devices provided in Schedule “A” and registered as drug qualifying above said criteria are being treated registered as medical devices under the Medical Devices Rules, 2015. This has improved the availability of registered medical devices to the users to a larger extent. Medical Devices other than life saving are exempted for six months under the said SRO and are freely available in the market.

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

**Item No.III. REVISION OF MEDICAL DEVICES RULES, 2015.**

The Board was briefed regarding revision of Medical Devices Rules, 2015 as follow:

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 has been constituted on 21st March, 2017 to review the existing Medical Devices Rules, 2015 in order to make them implementable. Up till now 3 meetings of the committee have been held on 28th March, 2017, 19th April, 2017 and 18th May, 2017. Preliminary recommendations of the committee in its First meeting are as follows:-

1. Medical devices defined as drugs under the Drugs Act, 1976 and the DRAP Act, 2012 may be considered for amendments in definition of “Drug” in DRAP Act, 2012 for redefining these as medical devices as per international practices. This matter be dealt separately being an amendment in the Act.
2. DRAP will review the existing fee structure of medical devices taking into consideration the regional and international practices and facts of the matter and cost effectiveness to both stakeholders and DRAP functionaries.
3. Indenting for import of medical devices shall be allowed for government institutes and a mechanism shall be devised in the said rules with ensuring restriction on any mal- practice.
4. Rules in regards to Conformity Assessments Bodies for establishments and their medical devices shall be reviewed.
5. The panel of inspectors of DRAP shall endorse Good Distribution Practices for Medical Devices (GDPMD) for medical devices establishments having Drug Sale Licence.
6. The importers shall print manufacturing date on their medical devices in order calculate shelf life at their licensed premises (for manufacturing license or sale licence). A provision also be added in new rules for very short expiry medical devices.
7. 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. The deliberation will continue in the next meeting.
8. Variation as approved in the country of origin shall be accepted by the DRAP as variation change.
9. The stake holders will send their consolidated proposals for amendment of specific rules in the Medical Devices Rules, 2015 by 7th April, 2017.
10. Medical Device Division of DRAP shall prepare draft rules which shall be presented in the next meeting to be held in the third week of April, 2017, where these draft amended rules will be thoroughly discussed.

**Decision: Draft amended Rules were placed before the Board. Each amendment was discussed in length and the Board agreed with amendments with few valuable suggestions which will be taken care in the draft rules.**

**Item No. IV.** **IT BASED NATIONAL REGISTRY FOR CARDIAC STENTS**

Under SRO. 167(I)/2017, DRAP has also launched and activated the first IT based National Registry for cardiac stents which shall provide a mechanism for manufacturers / importers and Cath Laboratories to compulsory enter the data of manufacturing / importation and utilization of cardiac stents in National Registry. Under the aforesaid SRO, all Cath Labs are required to be registered with the Pakistan Society of Interventional Cardiology (PSIC). Information of 18 importers of cardiac stents has been entered and verified by DRAP in the National Registry while Cath Labs shall enter utilization data of cardiac stents after registration with PSIC.

**Decision: The Board appreciated the efforts made by DRAP for successfully launching first IT based National Registry for cardiac stents.**

**Item No. V.** **MEDICAL DEVICES PROVIDED IN SCHEDULE-A AND ALREADY REGISTERED AS DRUGS.**

As per SRO.167(I)/2017, dated 15th March, 2017, the previous SROs declaring medical devices as drugs are repealed and all products registered under the provisions of previous SROs, if qualify the prescribed criteria in the said SRO, shall be deemed to be registered as medical devices under the Medical Devices Rules, 2015. It is submitted that already registered cardiovascular stents, peripheral stents, cardiovascular and peripheral catheters/balloons of different types are also provided in Schedule "A" of the new SRO. Most of these originate from reference countries mentioned in the SRO while some are from non reference countries. List of cardiovascular stents, peripheral stents, cardiovascular and peripheral catheters/balloons need to be considered by the Board which qualify the prescribed criteria, to be treated as registered medical device under the Medical Devices Rules, 2015.

**Decision: The Board discussed the case at length and was of the view that in the first instance list of Schedule "A" medical devices which were already registered as drug need to be finalized by the Board which qualify the prescribed criteria, to be treated as registered medical device under the Medical Devices Rules, 2015. In this regard the Board decided as follow:**

1. **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.**
2. **For those Schedule "A" medical devices already registered as drug, having valid registration, originating from reference countries mentioned in the SRO.167(I)/2017 but the firms have still not applied for Provisional Establishment Certificate, these firms shall be asked to apply for Provisional Establishment Certificate within 7 days otherwise further necessary action shall be taken by the MDB.**
3. **For those Schedule "A" medical devices already registered as drug, having valid registration but not originating from reference countries mentioned in the SRO.167(I)/2017, these firms shall be asked to provide original Free Sale Certificate of the subject product approved/allowed for free sale by any of the reference country mentioned in the SRO.167(I)/2017 or to provide Notarized CE Certificate of the product issued by EU notified body within 30 days of the issuance of letter otherwise under the aforesaid SRO, Schedule "A" medical devices are prohibited to be imported, sold or used in Pakistan except from aforesaid sources.**
4. **The MDB also decided that the medical devices previously declared as drug and are being manufactured through local manufacture shall continue to be registered as medical devices till their registration is valid. Thereafter, the firms shall apply for renewal on forms under the revised Medical Devices Rules and accordingly fresh registration number shall be allotted.**

**Item No. VI.** **TRANSFER OF REGISTRATION.**

M/s Asto Life Sciences Private Limited, Lahore has requested for transfer of following registered imported Medical Devices from the name of M/s Becton Dickinson Pakistan (Private) Limited, Lahore to their name:-

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| --- | --- | --- | --- | --- | --- |
| **S.#** | **Regn.No.** | **Brand Name of Medical Device** | **Packing** | **Shelf Life** | **Name of Manufacturer** |
| (i) | 074663 | BD SoloShot TM Mini Auto Disable Syringes | 0.5 ml  (23G, 24G & 25G)    0.05 ml  (27G X 3/8) | 5 years | M/s Becton Dickinson, S.A. Ctra, Mequinenza, Fraga (Huesca), Spain. |
| (ii) | 074685 | BD Emerald TM Pro (Reuse Prevention) Luer Slip Syringes | 2ml, 5ml & 10ml | 5 years | -do- |
| (iii) | 059218 | BD Disposable Syringes | 3ml, 5ml, 10ml, 20ml | 5 years | M/s Becton Dickinson Medical (Singapore) Tuas Avenue, Singapore. |
| (iv) | 059219 | BD Venflon TM Pro IV Cannulas | G16, G18, G20 & G22. | 5 years | -do- |

The firm has submitted following documents:-

1. Application dossier alongwith Form 5-A for each product.
2. Fee of Rs.100,000/- for each product.
3. Letters of Authorization regarding above products from the foreign manufacturer (legalized from High Commission of Pakistan/Embassy) wherein it has also been mentioned that M/s Asto Life Sciences (Private) Limited is authorized to submit the application for transfer of registration in their name to the Drug Regulatory Authority of Pakistan.
4. Original NOC from M/s Becton Dickinson Pakistan (Private) Limited, Lahore regarding transfer of registration of above products.
5. Change of address of M/s Becton Dickinson Pakistan (Private) Limited from 19 D/1, Gulberg-III, Lahore to 202-B, 2nd Floor, City Towers 6-K Main Boulevard, Gulberg-II, Lahore.
6. Copy of drug sale licence of M/s Asto Life Sciences Private Limited, Lahore.

It is submitted that as per Free Sale Certificate of BD Venflon TM Pro IV Cannula, product owner is Becton Dickinson Infusion Therapy AB Florettgatan 29C, PO Box 631, SE-251 06, Helsingborg, Sweden while manufacturing site is Becton Dickinson Medical (s) PTE Ltd, 30 Tuas Avenue 2, Singapore.

Case was placed before the Registration Board in 267th meeting and the Board deferred the case for provision of fresh NOC from M/s Becton Dickinson Pakistan (Private) Limited, Lahore. The decision of the Board was communicated to the firm.

The firm has now submitted the fresh NOCfrom M/s Becton Dickinson Pakistan (Private) Limited, Lahore.

**Decision: The Board approved transfer of registration of above products under Medical Devices Rules, 2015 from the name of previous agent M/s Becton Dickinson Pakistan (Private) Limited, Lahore to the name of new agent M/s Asto Life Sciences Private Limited, Lahore with correct name of manufacturer of BD Venflon TM Pro IV Cannula. All other conditions shall remain same. However, the firm M/s Asto Life Sciences shall apply for change of registration number after revision of Medical Devices Rules, 2015.**

**Item No. VII. EXTENSION IN SHELF LIFE FROM 18 MONTHS TO 24 MONTHS.**

M/s Ferozsons Laboratories, Nowshera has requested for extension in shelf life from 18 months to 24 months of their following already registered imported medical devices:-

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| --- | --- | --- | --- | --- |
| **S.No.** | **Regn. No.** | **Name of Drug (s)** | **Approved Shelf Life** | **Demanded Shelf Life** |
| (i) | 074716 | Promus Element Plus Monorail (Everolimus Eluting Coronary Artery Stent) Stent | 18 Months | 24 months |
| (ii) | 080719 | Promus Premier Monorail Everolimus Eluting Platinum Chromium Coronary Stent System. | 18 Months | 24 months |

The firm has submitted the stability justification summary as shelf life extension evidence for above mentioned products alongwith fee of Rs.5000/- for each product.

The case was placed before the Registration Board in its 267th meeting. The Board decided as follow:

" Registration Board approved the case. Firm will provide document for regulatory approval of change in shelf life from country of origin and Chairman, registration Board will authorize issuance of letter."

Later on the firm has provided stability study alongwith shelf life approval from notified body DEKRA. Approval letter for change of shelf life of above products was in process and in the meanwhile SRO. 167(I)/2017 was promulgated on 15-03-2017. Under new SRO, the previous SROs declaring medical devices as drugs are repealed and the approval letter could not be issued.

**Decision: The MBD approved the shelf life of above products from 18 month to 24 months. All other conditions shall remain the same.**

**Item No. VIII. AMENDMENT IN SCHEDULE-I OF THE DRAP ACT, 2012**

The Board was given briefing regarding amendment in the Schedule-I of the DRAP Act, 2012 under Section 35 (Power to amend Schedule) of the DRAP Act, 2012 to re-define sutures and other medical devices defined as drug as follow:

* 1. Certain medical devices like abortive and contraceptive devices, surgical ligatures, sutures, bandages, absorbent cotton and adhesive plasters have been defined as drugs under Section 3(g)(ii) of the Drug Act, 1976.
  2. The aforesaid medical devices are being accordingly regulated since 1976 under the Drugs Act, 1976. The prices of these devices are fixed by the Federal Government.
  3. The Drug Regulatory Authority of Pakistan Act, 2012 was promulgated on 13th November, 2012 for the establishment of Drug Regulatory Authority of Pakistan 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.
  4. The aforesaid medical devices have again been defined as drugs under sub-para (b) of para 2 of the schedule-I of the DRAP Act, 2012.
  5. Under the DRAP Act, 2012, Medical Device Rules, 2015 have been framed and notified on 9th March, 2015 for regulation of medical devices. Under these rules, medical devices have been classified as Class A, B, C and D medical devices on the basis of risk posed to patients wherein Class-D medical devices is the highest risk Class.
  6. Under rule 128 of the Medical Devices Rules, 2015, Class D, Class C, Class B and Class A (active, sterile or having measuring function) medical devices and establishments manufacturing or importing respective devices have been exempted from operations of these rules from its commencement till 30th September 2016, 8th December, 2016, 8th March, 2017 and 8th March, 2017 respectively. Prices of the medical devices as per rule 118 (a) of these rules fixed by the manufacturer and printed on the label/pack.
  7. Under rule 86 (2) of Medical Device Rules, 2015, all class A medical devices and establishments manufacturing, importing, exporting or selling Class A medical devices, other than those having measuring function, active or sterile, shall be regulated according to the enlistment rules to be notified by the Authority.
  8. During Human Rights Case No. 623-P/2017, 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. The said SRO has a Schedule “A” of 134 life saving medical devices which can be amended by the CEO, DRAP from time to time. 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 from issuance of this SRO.
  9. Regulatory authorities of European Union, USA and other stringent regulatory authorities regulate the aforesaid devices as medical device.
  10. Definitions of drugs and medical devices have been placed under schedule-I of the DRAP Act, 2012.
  11. Section 35 (Power to amend Schedule) of the DRAP Act, 2012 is reproduced as under:-

*“The Federal Government may, by notification in the official Gazette, amend the Schedule so as to add any entry thereto or modify or omit any entry therefrom on the recommendation of the Board”.*

The Policy Board in its 14th meeting held on 10th-11th September, 2015 has directed that “*procedure for categorization of sutures and other medical devices as Medical Devices that were earlier defined or declared as drugs shall be initiated, as soon as possible, in accordance with respective rules and international practices".*

The draft notification for amendment in the Schedule-I of the DRAP Act, 2012 under Section 35 (Power to amend Schedule) of the DRAP Act, 2012 to re-define sutures and other medical devices defined as drug was placed before the Authority in its 34th meeting held on 29th April, 2016. The Authority discussed the case in length and decided as follows:-

“The Authority agreed in principle for re-defining the suture and other medical devices, which were previously defined as drugs as medical devices under the Medical Devices Rules, 2015. Concerned Division was advised to initiate the process for amendments in the schedule-I and other legal issues shall be taken care off while re-defining these medical devices”.

Furthermore, as per recommendations of Prime Minister’s office meetings, a Committee under the chair of Additional Secretary, M/o NHS,R&C has been constituted on 21st March, 2017 to review the existing Medical Devices Rules, 2015 in order to make them implementable. During first meeting of the committee held on 28th March, 2017 the matter regarding redefining of sutures and other devices defined as drug was also discussed and the committee recommended as follows:-

“Medical devices defined as drugs under the Drugs Act, 1976 and the DRAP Act, 2012 may be considered for amendments in definition of “Drug” in DRAP Act, 2012 for redefining these as medical devices as per international practices. This matter be dealt separately being an amendment in the Act.”

**Decision: The Board agreed and recommended for amendment in the Schedule-I of the DRAP Act, 2012 under Section 35 (Power to amend Schedule) of the DRAP Act, 2012 to re-define sutures and other medical devices defined as drug in line with international regulations.**

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**EXPRACT TAKEN FROM 5TH MINUTES OF MDB HELD ON 25-05-2017**

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