**Government of Pakistan**

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

**Drug Regulatory Authority of Pakistan**

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**MINUTES OF THE 4TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**HELD ON 24TH MARCH, 2017.**

 4th meeting of the Medical Device Board (MDB) was held in the committee room of TF Complex, G-9/4, Islamabad on 24th March, 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. Walayat Shah,Senior Drug Inspector, Health Department, Khyber Pakhtunkhwa. | Ex-officio Member |
|  | Brig. (R) Dilshad Ahmed Khan, Professor of Pathology & Director Research, National University of Medical Sciences, Rawalpindi. | Member |
|  | Brig.(R) Dr. Waqar Azim Niaz, Consultant Urologist & Transplant Surgeon, Quaid-e-Azam International Hospital, Golra Mor, Islamabad.  | Member |
|  | Dr. Faridullah Khan Zimri, Health of Department, Orthopaedic & Physiotherapy Department, National Institute of Rehabilitation Medicine (NIRM), Islamabad. | Member |
|  | Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.  | Member |
|  | Miss. Tazeen S. Bukhari,TRF Technical Consultant for Medical Devices, Technical Resource Facility, 16-BB, Defence Housing Authority, Phase-IV, Lahore. | Member |
|  | Dr. Zaka-ur-Rehman, Chief Drug Inspector, Punjab Representative, DG (H), Punjab |  |

The Board nominated Dr. Ghazanfar Ali Khan, Deputy Director (MD) to present the agenda of the meeting in the absence of Secretary, MDB and assist the Chairman of the MDB while presenting the agenda before the Board.

 The meeting started with recitation of the Holy Quran.

**Item No. I.** **CONFIRMATION OF MINUTES OF 3RD MEETING OF THE MEDICAL DEVICES BOARD (MDB)**

**Decision**: The MDB confirmed the minutes of 3rd meeting of MDB.

**Item No. II**. **NOMINATION OF ANY OFFICER OF MEDICAL DEVICES DIVISION AS SECRETARY OF MDB UNDER RULE 135 (12) OF MEDICAL DEVICES RULES, 2015 AND PERFORMING DAY TO DAY BUSINESS.**

Rule 135 (12) Of Medical Devices Rules, 2015 is reproduced as under:-

 *“The Secretary of the MDB or any officer of the Medical Devices and Medicated Cosmetics Division nominated by the MDB may perform any specific function of the MDB including the disposal of its day-to-day business”*

 **Decision: The Board nominated Dr. Ghazanfar Ali Khan, Deputy Director (MD) to dispose depose day to day business of the Division and Medical Devices Board.**

**Item No. III. AUTHORIZATION OF ANY OFFICER OF MEDICAL DEVICE DIVISION IN THE ABSENCE OF SECRETARY TO SIGN THE ESTABLISHMENT LICENSE UNDER RULE 135 (14) OF THE MEDICAL DEVICES RULES, 2015.**

RULE 135 (14) Of Medical Devices Rules, 2015 is reproduced as under:-

 “*After approval of the MDB, the Secretary of MDB and in his absence due to any reason any officer of the Division authorized by the MDB shall sign the establishment licence and the registration certificate.”*

 **Decision: The Board authorized its Chairman for approval for issuance of provisional establishment license and acknowledgment of provisional registration application of medical device. After approval by the Chairman MDB, provisional establishment license or acknowledgment of provisional registration application of medical device may be signed by the Chairman himself or his authorized officer of the Division.**

**Item No.IV. BRIEFING REGARDING HUMAN RIGHTS CASE NO. 623-P/2017 IN THE SUPREME COURT OF PAKISTAN AND DECISIONS TAKEN AND NOTIFICATION ISSUED.**

The MDB was briefed regarding Human Rights Case No.623-P/2017 in the Supreme Court of Pakistan and decisions taken and notification issued as follow:-

1. In pursuance of subject proceedings in the Honorable Supreme Court of Pakistan in a Human Rights Case No. 623-P/2017, the Honorable Court noticed that patients and other stake-holders were facing difficulties in the usage of unregistered medical devices specifically stents and were confronting other malpractices as well including irrational, restrictive and exorbitant prices of cardiac stents.

2. On the directions of the Honorable Supreme Court of Pakistan on March 2, 2017, Prime Minister’s office convened two extensive meetings stretching to several hours involving all the relevant stakeholders including Ministry of National Health Services, Regulations & Coordination, officials of Federal and Provincial Governments, Provincial Healthcare Commissions, Drug Regulatory Authority of Pakistan, Additional Attorney General, Ministry of Science & Technology, Pakistan National Accreditation Council, National University of Science & Technology, Federal Investigation Agency, Federal Board of Revenue, Medical Devices Associations, Advocates of Supreme Court, Cardiac Societies, Cardiologists and Conformity Assessment Bodies chaired by Secretary to the Prime Minister were held on 6th March and 10th March, 2017 and after detailed deliberations to arrive at a practicable and implementable solution, following decisions/recommendations were made:

1. A notification shall be drafted by Ministry of NHS,R&C and Additional Attorney General Mr. Waqar Rana under powers conferred by section 36 and other enabling provisions of the Drug Regulatory Authority of Pakistan Act, 2012, in order to remove difficulties in the public interest, whereby Federal Government may direct that all medical devices, which were required to be registered under Medical Devices Rules, 2015 but had so far not been registered due to the exemption granted under Rule 128 of the afore-said Rules or otherwise shall be deemed to be registered subject to **submission of application along with original free sale certificate** and allowed to be imported, sold or used for medical purposes throughout Pakistan, if the said medical devices are approved for use and sale by the **regulatory authorities of the reference countries as provided under Rule 142 of the Medical Devices Rules, 2015** **or CE authorized based on the certificates issued by CABs notified by European Union Directive: 93/42/EEC which may be amended by the Chief Executive Officer**, Drug Regulatory Authority of Pakistan, from time to time, in accordance with revision by European Union authorities.
2. SRO 324 (I)/ 94 dated 19th April, 1994, SRO No.957(I)/2009 dated 5th November 2009 and SRO 349(I)/2010 dated 18th May, 2010 and SRO 919(I)/10 dated 01.10.2010 shall be repealed under Rule 146 of Medical Device Rules, 2015 and on issuance of proposed notification, all products registered under the provisions of aforementioned SROs, if qualify on above said criteria, shall be deemed to be registered as medical devices under the Medical Device Rules, 2015.
3. A schedule shall be developed containing life saving medical devices which cannot be imported, sold or used in Pakistan except from above sources. Medical devices other than those provided in schedule may be proposed to be exempted from the operation of the Medical Device Rules, 2015 for a period of 06 months from issuance of proposed notification. This Schedule may be amended by Chief Executive Officer, Drug Regulatory Authority of Pakistan from time to time. As an immediate step, the schedule may include life saving cardiac related devices and life saving medical devices of other specialties can be included subsequently. The power of amendments (addition or deletion) of life saving medical devices in the schedule may be entrusted to CEO, DRAP.
4. Regarding **establishment license application as prescribed by Medical Device Board**, from importers of above referred medical devices, Medical Devices Board (MDB) shall issue **provisional establishment certificate for a period of 06 months**, **within seven (07) working days, on production of original valid authorized agency agreement.**
5. DRAP shall develop a **national registry within 30 days** for cardiac stents and provide a mechanism for an authentic data base. For this purpose, **Cath labs shall be registered with Society of Interventional Cardiologists.**
6. A **policy directive** under section 41 of the DRAP Act, 2012 is proposed to be issued by the Federal Government; whereby following may be directed:
7. The manufacturers/ importers of Cardiac Stents shall print Maximum Retail Price (MRP) on the label of cardiac stents and widely disseminate the MRPs of their brand of Cardiac Stents and also publicize the same on their websites and in the print media on quarterly basis.

b. All the manufacturers/ importers of cardiac stents shall display a price list on a conspicuous place of the premises of the healthcare establishments performing cardiac procedures and healthcare establishments shall facilitate displaying the same, so that it is known to all concerned including doctors performing the procedure and the patients or their representatives who wish to consult the same.

c. The healthcare establishments performing cardiac procedures using cardiac stents shall specifically and separately maintain the price of cardiac stents along with brand name of its manufacturers/ importers, batch number, serial No., expiry date and other details, if any, in their billing to the patient or their representative.

d. The healthcare establishments/ Cath labs performing cardiac procedures using cardiac stents shall ensure making video recording of the whole procedure; copies of the procedure be handed over to the patient or his/ her representative, and to the Society of Interventional Cardiologists while one be kept for record of the Cath lab.

e. The Interventional Cardiologists Society shall prepare appropriate rules/ regulations to regulate Cath labs to achieve the objectives of safe use of stents, fair practices and patient safety.

1. A committee shall be constituted by the Ministry of National Health Services, Regulations & Coordination to review the existing Medical Devices Rules, 2015 in order to simplify the said Rules within 3-months and make those practical and implementable considering the capacity of DRAP. The committee may comprise of the following:

|  |  |  |
| --- | --- | --- |
|  | Additional Secretary, M/o, NHS,R&C  | Chair |
|  | CEO, DRAP | Member |
|  | Mr. Waqar Rana, Additional Attorney General or his representative | Member |
|  | Joint Secretary (IA-I), PM Office | Member |
|  | Special Secretary, Health Department, Government of Sindh | Member |
|  | Chief Drug Controller, Health Department, Government of Punjab | Member |
|  | Mr. Osman Waheed of Ferozsons Laboratories | Member |
|  | Mr. Hanif Sattar, representative of PCDA | Member |
|  | Dr. Zafar Hashmi, representative of Pharma Bureau. | Member |
|  | Mr. Shakeel Ahmed, representative HDAP | Member |
|  | Mr. Masood Ahmed from Pakistan Diagnostic Association | Member |
|  | Mr. Ahmed Ali Aslam from PCDIA | Member |
|  | Dr. Sheikh Akhter Hussain, Director (MD&MC), DRAP | Member/Secretary |

3.To implement the recommendations of the stakeholders, the same were placed before the Federal Cabinet for its approval and subsequently after the approval, **SRO along with Schedule “A”** containing list of life saving cardiovascular and allied medical devices under section 36 of DRAP Act, 2012 has been issued on 15-03-2017 by the Ministry **(Annex –I)**. This schedule is a dynamic list of life saving devices that can be added /deleted as per need / review and CEO, DRAP has been authorized under aforesaid notification to amend from time to time.

4. The Ministry has also issued a directive to the Policy Board and Drug Regulatory Authority of Pakistan Policy under Section 41 of DRAP Act, 2012 to check irrational, restrictive and exorbitant prices of the cardiac stents **(Annex-II)**.

5. Accordingly, in pursuance to 7(a), (f) & (y) of the DRAP Act, 2012, the Drug Regulatory Authority of Pakistan shall issue an advisoryto the Provincial Governments and all concerned for taking following measures to check the irrational, restrictive, exorbitant prices and huge unethical profiteering in cardiac stents in their respective Healthcare Establishments, Medical Institutions, Hospitals, Cath Laboratories, Organizations etc., engaged in performing of cardiac procedures including stenting in public and private sector:

i) to ensure that the importers of cardiac stents print maximum retail price (MRP) on the label of cardiac stents and are widely disseminating the MRP of their product brands of cardiac stents and also publicizing the same on their website and in the print media with updating on quarterly basis;

ii) to ensure that all the importers are displaying a price list of cardiac stents on a conspicuous part of the premises of the healthcare establishments (in public and private sector) performing cardiac procedures and that the healthcare establishments are facilitating the same so that it is known to all concerned including doctors performing the procedure and the patients or their representatives who wish to consult for the same;

iii) to ensure that healthcare establishments (in public and private sector) performing cardiac procedures using cardiac stents are specifically and separately maintaining the price of cardiac stents along with brand names(s) of its manufacturer(s) and importer(s), batch number, serial number, expiry date and other details, if any, in their billing to the patient or their representative;

iv) to ensure that healthcare establishments (in public and private sector) performing cardiac procedures using cardiac stents are making video recording of the whole procedure, making copies and handing over one to the patient or his / her representative, one copy to Pakistan Society of Interventional Cardiology while one for record of the Cath Laboratory;

v) to ensure that the Pakistan Society of Interventional Cardiology is preparing appropriate rules / regulations to regulate Cath Labs to achieve the objectives of safe use of stents, fair practices and patient safety and these are applied practically.

6. Office order for constitution of committee to review and amend Medical Devices Rules, 2015 has also been issued on 21-03-2017 and the first meeting will be held on **28th March, 2017**.

7. DRAP has initiated the process of establishing IT based registry and efforts shall be made to establish it within given timelines. It is hoped that due to above mentioned steps and decisions taken in the public interest, the difficulty being faced by the stakeholders in the use of medical devices shall be resolved.

**Item No. V.** **APPLICATION FORM FOR GRANT OF PROVISIONAL ESTABLISHMENT CERTIFICATE TO IMPORT MEDICAL DEVICES PROVIDED IN SCHEDULE “A”**

In pursuance of SRO issued on 15-03-2017 by the Federal Government along with Schedule “A” containing list of life saving cardiovascular and allied medical devices under section 36 of DRAP Act, 2012, format of **Application form for grant of Provisional establishment certificate to import medical devices provided in schedule “A”** was placed before the Authority in its 46th meeting held on 17th March, 2017. The authority has acceded to in principle the below mentioned form and is submitted for consideration and approval of MDB please:

**FORM-1**

**[**see SRO ---- dated 15th March, 2017**]**

**APPLICATION FORM FOR GRANT OF PROVISIONAL ESTABLISHMENT CERTIFICATE TO IMPORT MEDICAL DEVICES PROVIDED IN SCHEDULE “A”**

I/We ………………………..of M/s……………..hereby apply for grant of provisional establishment certificate to import medical devices provided in schedule “A” at the premises situated at …………….

|  |  |  |
| --- | --- | --- |
| S.No | Requirements | To be filled by the applicant |
|  | Establishment name and address including godown address: |  |
|  | Type of ownership and copy of business registration as issued by the Registrar of Companies, Security Exchange Commission of Pakistan or any other authorized body (Proprietorship, partnership, private limited, public limited, etc) alongwith names and address of partners/proprietors/directors (attached 4 photographs and CNIC of each): |  |
|  | Name, qualification, registration No, CNIC No. and address of qualified person(s)/technical person(s) for supervising import, sale and distribution (attach 4 photographs, CNIC and copy of Registration certificate) and copy of drug sale licence issued by provincial government): |  |
|  | Original bank deposit slip: |  |
|  | Original and valid authorized agency agreement from manufacturer(s) aboard: |  |
|  | Copy of Import Licence:  |  |

 **DECLARATION**

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

**UNDERTAKING**

I/we also undertake that I/we;

1. shall comply with the provisions of Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under;
2. shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any medical device in violation of the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

Name(s) of partners/proprietors/directors/ authorized person………………

Designations…………..

Signature(s)……………..

Stamp…………………..

Date…………………….

**Note:** Incomplete application shall not be entertained and shall not be considered as submitted.

**Decision: After thorough deliberations following Form was approved:**

**FORM-1**

**[**see SRO167/2017 dated 15th March, 2017**]**

**APPLICATION FORM FOR GRANT OF PROVISIONAL ESTABLISHMENT CERTIFICATE TO IMPORT MEDICAL DEVICES PROVIDED IN SCHEDULE “A”**

I/We ………………………..of M/s……………..hereby apply for grant of provisional establishment certificate to import medical devices provided in schedule “A” at the premises situated at …………….

|  |  |  |
| --- | --- | --- |
| S.No | Requirements | To be filled by the applicant |
|  | Establishment name and address including godown address: |  |
|  | Type of ownership and copy of business registration as issued by the Registrar of Companies, Security Exchange Commission of Pakistan or any other authorized body (Proprietorship, partnership, private limited, public limited, etc) alongwith names and address of partners/proprietors/directors (attached 4 photographs and CNIC of each): |  |
|  | Name, qualification, registration No, CNIC No. and address of qualified person(s)/technical person(s) for supervising import, sale and distribution (attach 4 photographs, CNIC and copy of Registration certificate) and copy of drug sale licence issued by provincial government): |  |
|  | Original bank deposit slip: |  |
|  | Original and valid authorized agency agreement from manufacturer(s) aboard: |  |

 **DECLARATION**

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

**UNDERTAKING**

I/we also undertake that I/we;

1. shall comply with the provisions of Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under;
2. shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any medical device in violation of the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

Name(s) of partners/proprietors/directors/ authorized person………………

Designations…………..

Signature(s)……………..

Stamp…………………..

Date…………………….

**Note:** Incomplete application shall not be entertained and shall not be considered as submitted.

**Item No. VI.** **APPLICATION FORM FOR PROVISIONAL REGISTRATION OF A MEDICAL DEVICE FOR IMPORT PROVIDED IN SCHEDULE “A”**

In pursuance of SRO issued on 15-03-2017 by the Federal Government along with Schedule “A” containing list of life saving cardiovascular and allied medical devices under section 36 of DRAP Act, 2012, format of **Application form for provisional registration of a medical device for import provided in schedule “A”** was placed before the Authority in its 46th meeting held on 17th March, 2017. The authority has acceded to in principle the below mentioned form and is submitted for consideration and approval of MDB please:

**FORM-2**

[seeSRO --- dated 15th March, 2017**]**

**APPLICATION FORM FOR PROVISIONAL REGISTRATION OF A MEDICAL DEVICE FOR IMPORT PROVIDED IN SCHEDULE “A”**

I/We (name(s) and designation)………………………..of M/s……………..hereby apply for Provisional Registration of medical device for import provided in schedule “A”, namely …………………,details of which are mentioned below along with enclosures.

|  |  |  |
| --- | --- | --- |
| S.No | Requirements | To be filled by the applicant |
|  | Details of importer:1. Name of establishment:
2. Complete address and contact information as telephone numbers, fax numbers, email addresses, official websites, etc :
3. Provisional Establishment Certificate number and date of issuance (attach copy of Provisional Establishment Certificate):
 |  |
|  | General Information:1. Medical device brand name, non-proprietary name, type:
2. Original and valid Free sale certificate from regulatory authorities of reference countries mentioned in rule 142 of the Medical Devices Rules, 2015 or valid CE authorized based on the certificates issued by CABs notified by European Union Directive:93/43/EEC:
3. Copy of valid authorized agency agreement with manufacturer abroad:
4. Original Bank deposit slip:
 |  |
|  | Information of manufacturer:1. Name and Address of Manufacturer aboard as per free sale certificate:
 |  |

**DECLARATION**

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

**UNDERTAKING**

I/we also undertake that I/we;

1. shall comply with the provisions of Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under,
2. shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any medical device in violation of the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

Name(s) of partners/proprietors/directors/ authorized person………………

Designation………….

Signature……………..

Stamp……………….

Date……………….

**Note:** Incomplete application shall not be entertained and shall not be considered as submitted.

**Decision: After thorough deliberations following Form was approved:**

**FORM-2**

[seeSRO.167/2017 dated 15th March, 2017**]**

**APPLICATION FORM FOR PROVISIONAL REGISTRATION OF A MEDICAL DEVICE FOR IMPORT PROVIDED IN SCHEDULE “A”**

I/We (name(s) and designation)………………………..of M/s……………..hereby apply for Provisional Registration of medical device for import provided in schedule “A”, namely …………………,details of which are mentioned below along with enclosures.

|  |  |  |
| --- | --- | --- |
| S.No | Requirements | To be filled by the applicant |
|  | Details of importer:1. Name of establishment:
2. Complete address and contact information as telephone numbers, fax numbers, email addresses, official websites, etc :
3. Provisional Establishment Certificate number and date of issuance (attach copy of Provisional Establishment Certificate):
 |  |
|  | General Information:1. Medical device brand name, non-proprietary name, type:
2. Original and valid Free sale certificate from regulatory authorities of reference countries mentioned in rule 142 of the Medical Devices Rules, 2015 or valid CE authorized based on the certificates issued by CABs notified by European Union Directive:93/43/EEC:
3. Copy of valid authorized agency agreement with manufacturer abroad:
4. Original Bank deposit slip:
 |  |
|  | Information of manufacturer:1. Name and Address of Manufacturer aboard as per free sale certificate:
 |  |

**DECLARATION**

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

**UNDERTAKING**

I/we also undertake that I/we;

1. shall comply with the provisions of Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under,
2. shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any medical device in violation of the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

Name(s) of partners/proprietors/directors/ authorized person………………

Designation………….

Signature……………..

Stamp……………….

Date……………….

**Note:** Incomplete application shall not be entertained and shall not be considered as submitted.

**Item No. VII.** **PROVISIONAL ESTABLISHMENT CERTIFICATE TO IMPORT MEDICAL DEVICES** **PROVIDED IN SCHEDULE “A”**

In pursuance of SRO issued on 15-03-2017 by the Federal Government along with Schedule “A” containing list of life saving cardiovascular and allied medical devices under section 36 of DRAP Act, 2012, format of **Provisional establishment certificate to import medical devices**  **provided in schedule “A”** was placed before the Authority in its 46th meeting held on 17th March, 2017. The authority has acceded to in principle the below mentioned form and is submitted for consideration and approval of MDB please:

**FORM-3**

**[**SRO ---- Dated 15th March, 2017**]**

**DRUGS REGULATORY AUTHORITY OF PAKISTAN**

**PROVISIONAL ESTABLISHMENT CERTIFICATE TO IMPORT MEDICAL DEVICES**  **PROVIDED IN SCHEDULE “A”**

Provisional Establishment Certificate No. Date of issue:

 M/s………………..situated at……………is hereby issued Provisional Establishment Certificate being importer of medical devices provided in schedule “A” and being authorized agent of manufacturer(s) M/s………………..

2. This Provisional Establishment Certificate permits the import and wholesale of medical devices provided in Schedule “A” subject to compliance of SRO--- dated 15th March, 2017.

3. Name(s) of partners/proprietor(s)/director(s)/ MD/CEO along with CNIC Number(s)

1. …………………………..
2. ………………………….

4. Name(s) of the qualified/technical person(s) incharge who will personally supervise the import and sale of medical devices by way of wholesale along with registration No. and CNIC No.

1. …………………………..
2. ………………………….

5. Addresses of godowns (licenced premises) where medical devices shall be stored ………

6. The certificate will be in force for a period of 6 months from the date of issue unless earlier suspended or cancelled.

7. This certificate shall be subject to regulatory conditions including the following conditions namely:-

1. No medical device requiring special storage conditions of temperature and humidity shall be stored or sold unless the precaution necessary for preventing the properties of the components have been observed throughout the period during which it remained in possession of the licensee.
2. The importer shall be responsible for the quality, efficacy and safety of all the medical devices imported and sold by him.
3. He shall abide by all the provisions of the Drug Regulatory Authority of Pakistan Act, (XXI) of 2012 except those exempted under the said Act and SRO--- dated 15th March, 2017.
4. He shall immediately recall the defected and unsafe medical devices within 15 days after intimation to him and report the compliance to the Authority.
5. Provisional Establishment Certificate shall be surrendered to the Authority within 7 days if it is suspended, revoked or its holder winds up his business.
6. The importer shall print MRP on the label of medical devices for patient information.
7. Any other relevant condition imposed by the Authority in future.

 Secretary

Medical Device Board

 Seal:

**Decision: After thorough deliberations following Form was approved:**

**FORM-3**

**[see** SRO 167/2017 dated 15th March, 2017**]**

**DRUGS REGULATORY AUTHORITY OF PAKISTAN**

**PROVISIONAL ESTABLISHMENT CERTIFICATE TO IMPORT MEDICAL DEVICES**  **PROVIDED IN SCHEDULE “A”**

Provisional Establishment Certificate No. Date of issue:

 M/s………………..situated at……………is hereby issued Provisional Establishment Certificate being importer of medical devices provided in schedule “A” and being authorized agent of manufacturer(s) M/s………………..

2. This Provisional Establishment Certificate permits the import and wholesale of medical devices provided in Schedule “A” subject to compliance of SRO--- dated 15th March, 2017.

3. Name(s) of partners/proprietor(s)/director(s)/ MD/CEO along with CNIC Number(s)

1. …………………………..
2. ………………………….

4. Name(s) of the qualified/technical person(s) incharge who will personally supervise the import and sale of medical devices by way of wholesale along with registration No. and CNIC No.

1. …………………………..
2. ………………………….

5. Addresses of godowns (licenced premises) where medical devices shall be stored ………

6. The certificate will be in force for a period of 6 months from the date of issue unless earlier suspended or cancelled.

7. This certificate shall be subject to regulatory conditions including the following conditions namely:-

1. No medical device requiring special storage conditions of temperature and humidity shall be stored or sold unless the precaution necessary for preventing the properties of the components have been observed throughout the period during which it remained in possession of the licensee.
2. The importer shall be responsible for the quality, efficacy and safety of all the medical devices imported and sold by him.
3. He shall abide by all the provisions of the Drug Regulatory Authority of Pakistan Act, (XXI) of 2012 except those exempted under the said Act and SRO--- dated 15th March, 2017.
4. He shall immediately recall the defected and unsafe medical devices within 15 days after intimation to him and report the compliance to the Authority.
5. Provisional Establishment Certificate shall be surrendered to the Authority within 7 days if it is suspended, revoked or its holder winds up his business.
6. The importer shall print MRP on the label of medical devices for patient information.
7. Any other relevant condition imposed by the Authority in future.

 Secretary

Medical Device Board

 Seal:

**Item No. VIII. FEE FOR APPLICATION FORM FOR GRANT OF PROVISIONAL ESTABLISHMENT CERTIFICATE TO IMPORT MEDICAL DEVICES PROVIDED IN SCHEDULE “A” AND APPLICATION FORM FOR PROVISIONAL REGISTRATION OF A MEDICAL DEVICE FOR IMPORT PROVIDED IN SCHEDULE “A”**

In pursuance of SRO issued on 15-03-2017 by the Federal Government along with Schedule “A” containing list of life saving cardiovascular and allied medical devices under section 36 of DRAP Act, 2012, the case for fee for application form for grant of provisional establishment certificate to import medical devices provided in schedule “A” and application form for provisional registration of a medical device for import provided in schedule “A” was placed before the Authority in its 46th meeting held on 17th March, 2017. The authority has acceded to in principle that the firms shall submit 50% fee of already prescribed fee in Medical Devices Rules, 2015 for both cases. Remaining 50% fee shall be submitted at the time of applying for Establishment Licence and medical device registration.

**Decision: The Board approved the above proposal and decided that the firms shall submit 50% fee of already prescribed fee in Medical Devices Rules, 2015 for both cases. Remaining 50% fee shall be submitted at the time of applying for Establishment Licence and Medical Devices Registration.**

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

 During 38th meeting of Drug Regulatory Authority of Pakistan it was discussed that under Medical Devices Rules, 2015 Medical Device Board shall issue following type of licenses:-

1. License to manufacture medical devices.
2. License to import medical devices.

 It is submitted that Medical Device Board has been established vide notification No.F.15-3/2015-MD, dated 30th October, 2015 responsible for the above mentioned licenses. The medical device manufacturing unit has been granted the license to manufacture drugs under Drug Act, 1976 before the promulgation of Medical Devices Rules, 2015. It was discussed that on the same analogy as exemption was granted to the CABs may also be adopted for already issued licenses under the Drugs Act, 1976. The Authority decided as under:-

“*The Authority approved that the proposal for exemption of already issued licenses of medical devices manufacturers granted under the category of drugs, shall be processed for exemption of establishment license under Medical Devices Rules, 2015, accordingly. At the time of renewal, applications may be processed under Medical Devices Rules, 2015, in case if the CAB & other matters are resolved.”*

**Decision: The Board decided that Licensing units shall be requested to handover all the files 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.**

**Item No. X. FATE OF APPLICATIONS FOR REGISTRATION OF MEDICAL DEVICES DECLARED AS DRUG APPLIED UNDER Drug ACT, 1976.**

 Before issuance of SRO 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 from 15th March, 2017 and all earlier medical devices declared as drugs shall now be regulated as medical devices under Medical Devices Rules, 2015. The firms prior to repeal of medical devices declared as drugs applied on Form 5-A under Drugs (Licensing, Registering & Advertising) Rules, 1976, which are under process/pending.

**Decision: The Board decided that all under process/pending applications of medical devices applied as drugs on Form 5A of Drugs (L, R and A) Rules, 1976 shall be processed under medical devices rules subject to fulfillment of requirements under medical device rules and prescribed 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 deficient fee as prescribed under medical devices rules.**

The meeting ended with vote of thanks to and from the Chairman

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