JDC(I)/Misc/05/2018
Central Drugs standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare

Dated: 16.03.2018

Circular for additional attention

Subject: Additional information regarding Medical Device Rules 2017-regarding

In addition to various clarifications issued by this office regarding Medical Device Rules 2017 in the form of FAQ's, the stakeholders may refer to the additional information listed below:-

1. **If a license is granted in Form 25 or Form 28 before or after publication of GSR 1337(E) dated 27.10.2017, what will be validity period of such licence?**

- As per notification, GSR 1337(E), dated 27.10.2017 the licence issued under Form 25 or 28, unless sooner suspended or cancelled, shall remain valid perpetually.

2. **What will be status of application for renewal of licence issued in Form 25 or Form 28 which are pending for approval by licensing authority or central licensing approving authority on or after 27.10.2017?**

- As per notification, GSR 1337(E), dated 27.10.2017, the Drugs and Cosmetic Rules, As per provisions in Rule 75 and Rule 76 the word "renewal" is omitted however, the licensee shall deposit licence retention fee and documents as per the provisions of Current Medical Device Rules 2017.

  It is advised to all manufacturers of medical devices for compliance with the conditions and with the requirements of Medical Devices Rules, 2017 by online processes before the due date of the payment of applicable license retention fee.

3. **What will be the status of the application for grant of licence which are applied before 01.01.2018 but are still in process and not granted the licence?**

- The application for grant of licence which are applied before 01.01.2018 but are still in process and not granted the licence, the applicant will need to pay balance fees and also reapply on the online portal as per the Current Medical Device Rules 2017.

4. **What will be the status of manufacturing license / additional product issued by State Licensing Authority before 01.01.2018 and sent for approval to CLAA?**

- Manufacturing licences of a medical devices covered under CLAA scheme and signed for granting by State Licensing Authority before 31.12.2017, may be considered for approval by CLAA with the condition that licensee shall fulfill requirements of Medical Devices Rules, 2017 after 01.01.2018. Further, if such licenses are signed by State Licensing Authority after 27.10.2017, it shall be granted in accordance with GSR 1337 dated 27.10.2017 and those which are signed by SLA before 27.10.2017 shall be granted as per earlier provisions with validity period.

5. **What will be the status of application for additional products on old existing licence in similar category, made after 01.01.2018 which are not yet issued?**

- For inclusion of additional products on existing licence as per practices followed, additional fees and documents will have to be submitted as per current Medical Device Rules 2017.

6. **What will be status of those applicants for import, who applied for registration or Import License before 01.01.2018 on old Sugam, but could not get it, due to incompletion of document or query raised?**

- Such applicants shall re-apply in new CDSCO MD online portal with additional balance fees and documents as per Medical Devices Rules, 2017 which may include new application form, new Power of Attorney, covering letter detailing the sequence of event & proofs thereof including proof of old fees paid. Such old applications on old Sugam may get advantage of old submissions/ fees till 30.07.2018 based on Medical Devices Rules, 2017.

7. **What will be applicability /utility of old sugam for applicants, with respect to existing Registration Certificate/ import Licenses?**

- Old sugam will remain operative for additional product endorsement, post approval changes of existing Registration Certificate and Import Licenses (as on 1.1.2018) till their expiry or till 30.07.2017, whichever is later as per Medical Devices Rules, 2017.

8. **For importing of raw materials / components intended to be used for further manufacture of Finished Medical Devices under a valid manufacturing licence**

issued under the provisions of Drugs and Cosmetic Act and Rules thereunder, whether the importer needs to obtain the import license for such raw materials / components ?

- As per existing practices and circulars, in such cases, no import licence is required.

9. **What will be the status of competent person existing on the licence before 01.01.2018 for manufacturing and testing?**

- As per the saving clause of Rule 97 prescribed in Medical Devices Rules, 2017 those competent persons will continue to remain so.

For details the stake holders may also refer to Medical devices and Diagnostics section in the CDSCO website.

(Dr. V.G. Somani)
Joint Drugs Controller (India)

To,

1. All Stakeholders through website of CDSCO
2. Zonal/Sub-Zonal offices of CDSCO
3. All officers of CDSCO (HQ)