Central Drugs Standard Control Organization
Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India

Central Drugs Standard Control Organization

(Medical Devices and Diagnostic Division)

Medical Devices (MD)

Frequently Asked Questions on Medical Device Rule, 2017

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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE

GOVT. OF INDIA

Notice:

The replies to the FAQs are aimed only for creating public awareness about Medical Devices Regulation by CDSCO and are not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act & Rules and respective Guidelines / Clarifications issued by CDSCO from time to time for all their professional needs

Frequently Asked Questions on Medical Device Rule,2017

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 procedure to obtain additional products on existing valid licences, in similar category of Medical Devices/IVD's after 01.01.2018?**

- **Application form, fees and documents will have to be submitted on new Medical Device portal as per MDR-2017 to obtain the new licence.**

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?**

8. **Old sugam will remain operative for post approval changes of existing Registration Certificate and Import Licenses (as on 1.1.2018) till their expiry or till 30.07.2018, whichever is later as per Medical Devices Rules, 2017.**

9. **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.**

10. **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.**

Note: ***The first nine questions and answers applies to IVD's also***

11. **By when will the revised Notified Medical Device listing be made available?**

- **As per Medical Device Rules 2017,**

(i) substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i);

(ii) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii); and
(iii) 15 classes of Medical devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) Government of India may notify more devices under section 3 (b) (iv) of the Drugs and Cosmetics Act, 1940 in due course of time which will be displayed on the CDSCO website.

12. Will business continuity be considered for devices already in market, but not yet notified, if they are brought under the list of notified devices?

- Once devices are brought under notified categories, the manufacturer / importer has to comply with Medical Device Rules 2017.

13. What would be the transition timeline given to manufacturers and importers w.r.t grandfathering of already existing devices?

- If the device is already in the market and government of India notify the same under 3(b)(iv) of Drugs and Cosmetics Act, 1940 (23 of 1940) then the device will be regulated under the Medical Device Rules 2017.

14. In which form permission to import small quantities of medical devices for personal use can be obtained?

- A patient can apply in Form MD-20 with all requisite documents and permission can be given in Form MD-21.

15. What is the process for classification verification with CDSCO or notified body prior to submission?

- The Central Licensing Authority shall, classify medical devices referred to in Rule 2, based on their intended use and other parameters specified in the First Schedule. Based on the classification referred to in sub-rule (3), class wise list of medical devices shall be published on the website of the Central Drugs Standard Control Organization (CDSCO): Provided that the Central Licensing Authority may, from time to time, make additions or deletions in such list of medical devices or modify the

class of any medical device. CDSCO has already displayed the list of medical devices with classification, which is dynamic in nature.

16. What if the classification of a product being imported is different in GHTF countries from the classification in India?

- In such cases, the higher class of Medical device will be considered.

17. Where can we get a list of authorized Notified bodies?

- The list of the registered Notified bodies with CDSCO will be made available on the website.

18. What are the requirements to be a registered Notified body?

- The requirements are laid down in Part I of Third Schedule of Medical Devices Rules, 2017.

19. Will the manufacturer have an option to choose Notified body?

- The Notified body accredited under sub-rule (1) of Rule 13 shall be competent to carry out an audit of manufacturing sites of Class A and Class B medical devices to verify their conformance with the Quality Management System and other applicable standards as specified under these rules in respect of such medical devices as and when so advised by the State Licensing Authority.

20. If Notified body is not having competency to evaluate specific class(es) of devices, what would be the process?

- As per the Medical devices Rules 2017, the National Accreditation Board for Certification Bodies (NABCB) shall lay down the conformity assessment activities for Accreditation of Notified bodies prior to registration with CDSCO.

21. For devices, already in market and notified later, would the requirement of local clinical investigation/evaluation be waived off?

- The medical device on the basis of their intended use will be deliberated on case to case basis & data available, to substantiate their safety and effectiveness. The matter may also be placed before SEC.

22. **Sub- clause (ii) lists 'insecticides' as notified under sub-clause (ii) of the 'Drugs' definition under clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) will be regulated under the Medical Device Rules 2017. In most cases, these are currently regulated as 'Drugs' and have FF-Finished Formulation Registration Certificates. Please clarify that under the new Rules, these product categories would also migrate to medical devices?**

- **As per the medical device definition the substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) are included in the definition of medical devices.**

23. **Sub- clause (ii) lists 'Insecticides' as notified under sub-clause (ii) of the 'Drugs' definition under clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) will be regulated under the Medical Device Rules 2017. In most cases, these are currently regulated as 'Drugs' and have FF-Finished Formulation Registration Certificates. Please clarify that under the new Rules, these product categories would also migrate to medical devices?**

- **As per the medical device definition the substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).**

24. **In the event CDSCO considers any devices to be regulated beyond the notified devices as additional devices or as subset of device, what will be the process of regulating such device?**

- **The devices which are already notified or to be notified by Government of India shall be regulated as per Medical Device Rules 2017.**

25. **Will a list of products classified into Class A, B, C and D be released by CDSCO or the companies have to do a self-classification of the products as per their understanding of the definition of the risk factors?**

- **List of devices based on risk classification is published on the CDSCO website which is dynamic in nature.**

26. If the list will be provided by CDSCO then would it be classified according to their therapeutic specialty (Cardiovascular, Dental etc.) to provide ease of location of the product?

- **Yes, the devices are classified as per the Risk based classification which is at par with the classification adopted in other countries is already displayed on the CDSCO website.**

27. Will the risk-based classification be harmonized with the already existing and established global classification systems?

- **Yes.**

28. Will a single import license fee apply to a grouped submission?

- **Any person who intends to apply for grant of licence in respect of medical devices for - (i) import; (ii) manufacture for sale or for distribution; and may group all or any medical device in accordance with the guidelines to be issued from time to time by the Ministry of Health and Family Welfare in the Central Government, by taking into consideration the technological changes or development in the field of medical devices and in vitro diagnostic medical devices. If the principle technology, platform, intended use and product specification are different then separate fees needs to be submitted.**

29. If a manufacturing firm is complying with ISO/IEC standards, would it still need to follow BIS standards?

- **(i) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.**

  (ii) Where no relevant standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.

  (iii) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

30. **Will a Notified body with two years auditing experience, outside India, be eligible for registering as a Notified body for carrying out audit of Class C & D medical devices?**

- **Yes, they have to be registered with NABCB and CDSCO before being considered for auditing.**

31. **What is the timeline for carrying out the inspection for class C & D and grant of licence?**

- **For class C and class D the inspection will be carried out by Central Licensing Authority within a period of 60 days from the date of application and Central Licensing Authority may grant licence if satisfied that the requirements of these rules have been complied within a period of forty five days from the date the inspection report has been received.**

32. **In case of Multi pack of a medical device is it sufficient to provide a single IFU (Instructions for use) if the medical devices are to be used by Health Care Professionals?**

- **The medical device when offered for sale shall be accompanied by either its package insert or user manual.**

33. **Will e-IFU (electronic Instructions for use) be permitted under the new regulations?**

- **In Medical Device Rules 2017, e-IFU is not specified.**

34. **Several low-risk medical devices are supplied without an IFU. Where such a low-risk device is offered for sale, an IFU is not applicable and may not be supplied. Will this be allowed if a justification is submitted to the licensing authority (LA) at any time of registration?**

- **The medical device when offered for sale shall be accompanied by either its package insert or user manual as per Rule 26 part (x) of Medical Device Rules 2017.**

35. **Could there be multiple importers for the same product (i.e. same legal & actual manufacturer)?**

- **Yes, an authorized agent having licence to manufacture for sale or distribution or wholesale licence for sale or distribution under these rules, shall make an application for grant of import licence for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a licence.**

36. In case of multiple importers for same product:

a. For subsequent applications to obtain import license for already registered product & site by another agent under Medical Devices Rules, 2017 do all the documents related to site and product need to be submitted?

- **The new agent has to submit the legal documents like MD-14, new Power of Attorney, fees, wholesale/manufacturing licenses, Label, IFU and copy of import licence issued to earlier agent along with the undertaking from the manufacturer stating that there is no change in the Device master file, Plant master file and other regulatory documents submitted to CDSCO by the earlier agent (name, address & Import License number) for registration.**

b. How will Post Marketing Surveillance (PMS) be managed? Who will have reporting responsibility?

- **PMS is the responsibility of the licensed holder/authorized agent.**

c. In case of new medical device does each applicant need to obtain investigational device approval or once first importer obtains the investigational device approval the subsequent importers can simply obtain Import license?

- **Every applicant viz. authorized agent or manufacture has to obtain separate investigational device approval for new medical devices.**

37. Would there be a provision to list multiple sites for a specific product on an existing certificate which has multiple products?

- **For the import of additional product from different manufacturing site the Indian agent has to submit fee for additional site as well as for the product and, the import licence will be issued with fresh validity. In case the importer desires to get endorsed the additional product then product fees is required to be submitted and the import license will be issued with the same validity as of the existing license.**

38. If yes, then what will be the procedure to endorse an additional manufacturing site (legal or actual) into an existing licence?

- **As explained in Q no. 34.**

39. What is the timeline for grant of approval for additional products from same site (in Form MD-15-Licence to import medical device)?

- As per Rule 36 sub-rule (1), the Central Licensing Authority may, on being satisfied, grant licence in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

40. What is the timeline for grant of approval for additional manufacturing site?

- As explained in Q no. 38.

41. In the event of an inspection of an overseas manufacturing facility, what is the expected timeline subsequent to date of submission?

- On receipt of an application under sub-rule

(i) of Rule 34, the Central Licensing Authority, may cause an inspection of the overseas manufacturing site either by itself or by any other person or body to whom the power has been delegated for the purpose.

(ii) The applicant shall be liable to pay a fee as specified under the Second Schedule in respect of expenditure required in connection with the visit to the overseas manufacturing site under sub-rule (1).

(iii) The Central Licensing Authority may, on being satisfied, grant licence in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

42. After completion of inspection of an overseas manufacturing facility what will be the Central Drugs Standard Control Organization's timeline for submitting their findings?

- The Central Licensing Authority may, on being satisfied, grant licence in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

43. If product is manufactured in countries other than the ones listed in Rule 36 sub-rule (3) – will clinical investigation in India be waived off for all classes?

- As per Rule-36 sub-rule (4) where a medical device is imported from countries other than those referred to in sub-rule (3), the licence in case of Class C and Class D medical devices may be granted after its safety and effectiveness has been established through clinical investigation in India as specified under provisions of Chapter VII of these rules.

Where a medical device, is imported from countries other than those referred to in sub-rule (3), the licence in case of Class A or Class B medical devices may be granted

after its safety and performance has been established through published safety and performance data or through clinical investigation in the country of origin and a free sale certificate from the country of origin is furnished.

44. Does the license retention fee need to be accompanied with any support documentation? If yes, what are these documents?

- The Firm needs to comply all the conditions laid down in the import license as per Rule 38.

45. Can Importer affix the India specific details as a sticker on retail pack in India or would the manufacturer be required to do so prior to shipping to India?

- As per Rule-44 (n) importer can provide the label, in case of imported devices, by way of stickering, when such details are not already printed, includes import licence number, name and address of the importer, address of the actual manufacturing premises and the date of manufacture.

46. Can the date of manufacture/sterilization/expiry be mentioned as DD/MM/YY or MM/YY?

- As per Rule- 44 (e) the date of expiry shall be in terms of the month and the year and it shall mean that the medical device is recommended till the last day of the month and the date of expiry shall be preceded by the words "Expiry date" or "Shelf Life".

47. Are labeling rules applicable on transparent covers or any wrapper, case or other covering which is used for the purpose of packing/transport or delivery?

- As per Rule-44 the particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed.

48. What are the satisfactory evidences to be provided to get approval for Shelf Life more than 5 years?

- Satisfactory accelerated and real time data as per international norms on the products including field samples should be provided.

49. To import a medical device which does not have a predicate would the clinical trial be waived off in the event of CE marking?

- No. The results of clinical investigation in India may not be required to be submitted where the investigational medical device is approved by the regulatory authorities of either the United Kingdom or the United States of America or Australia or Canada or Japan and the said device has been marketed for at least two years in that country and the Central Licensing Authority is satisfied with the data of safety, performance and pharmacovigilance of the device.

50. Will licences currently valid but expiring immediately after 1st Jan 2018 be considered valid until 31st July 2018 or 30th June 2019 as per Rule 97 'Savings'?

- As per Rule 97 (i) The licence or registration certificate, issued under the provisions of the Act and the Drugs and Cosmetics Rules, 1945, prior to commencement of these rules, shall be deemed to be valid till its expiry or for a period of eighteen months from the date these rules are notified, whichever is later, under the corresponding provisions of these rules.

51. Will the licence issued in 2017 having validity up to 2020 be valid till 2020 as per new Medical Device Rule 2017?

- As per Rule 97 (i) The licence or registration certificate, issued under the provisions of the Act and the Drugs and Cosmetics Rules, 1945, prior to commencement of these rules, shall be deemed to be valid till its expiry or for a period of eighteen months from the date these rules are notified, whichever is later, under the corresponding provisions of these rules.

52. For licences expiring in early 2018 does the firm need to submit renewal 9 months in advance or simply pay retention fee, on expiry, as specified in new rules?

- As per Rule 34 (1) An authorized agent having licence to manufacture for sale or distribution or wholesale licence for sale or distribution under these rules, shall make an application for grant of import licence for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a licence.

53. How would the import licence (with different RC holders) transit into the new system?

- As per Rule 34 sub-rule (1) Individual import licences have to be applied with requisite fees and documents.

54. What would be the mechanism for adding the new products in the existing registration certificate which will be valid after 1st Jan 2018 till 2020?

- **As per Rule 34 sub-rule (1) An authorized agent having licence to manufacture for sale or distribution or wholesale licence for sale or distribution under these rules, shall make an application for grant of import licence for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a licence.**

55. Will there be any provision to grant extended validity to the existing licences by paying the fee difference, few relevant undertakings and certificates instead of submitting the complete Device Master File (DMF) & Plant Master File (PMF)?

- **As per Rule 34 sub-rule (1) an authorized agent having licence to manufacture for sale or distribution or wholesale licence for sale or distribution under these rules, shall make an application for grant of import licence for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a licence.**

56. What fee would be applicable for the manufacturing site, if the importers wish to register devices belonging to multiple classes (A/B/C/D)?

- **As per the second schedule the Firm needs to submit the fee for different classes of the products. If the manufacturer is manufacturing all classes of the product then fees pertaining to higher class needs to be submitted.**

57. For cases, where real-time data is not available at the time of submission of application, accelerated stability for how many weeks or months to be submitted to support the claimed shelf life initially? Can we submit three months accelerated stability data as compliant with relevant ISO standards?

- **As per Fourth Schedule, part III, Appendix II (7.8); if available, real-time aging data shall be submitted to support the claimed shelf life. However, if real-time data is not available, accelerated stability data shall be submitted to support the claimed shelf life. Such a provisional claimed shelf life may be approved provided that the manufacturer immediately initiates real-time stability testing to validate the proposed shelf life. After completion of the real time stability analysis, real-time stability data shall be submitted in support of the claimed shelf life**

58. Does the requirement in the fourth schedule which specifies that the manufacturers have to submit an undertaking that they comply with the provisions of the fifth schedule applicable to application for license to manufacture?

- **Undertaking signed stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule needs to be submitted in case of manufacture of Class B, C and D medical devices.**

59. Is Fifth Schedule applicable for importers?

- **Fifth Schedule is applicable for manufacturers.**

60. Whether any change in labeling which is not among the details mentioned under Chapter- Labeling of medical devices (Rule 44) need to be notified? For e.g., if the label is universal for India and Philippines and there is change of manufacturing of license no. In the Philippines label part as per their local regulations, need to be notified?

- **Label excluding change in font size, font type, color, label design is a major change as per Sixth Schedule and prior approval needs to be taken from Central Drugs Standard Control Organization.**

61. Will change in authorized Agent require fresh License?

- **Change in Indian agent will require fresh License**

62. Whether GMP compliance and GMP certification is applicable to medical devices and IVDs as per Medical Devices Rules, 2017 as it ask for compliance to Quality Management System (QMS) & there is no mention of need for compliance to GMP?

- **As per Medical Devices Rules, 2017, there is no mention of requirement for compliance to GMP, but there is need for compliance to QMS and other rules. Therefore, now, there is no requirement of GMP certificates for Medical Devices & IVDs.**

63. Despite no mention in rule for domestic purposes, if requested by importing country, who will issue the WHO GMP certificate for medical devices and IVDs ?

- **Licensing Authority who has issued the valid license to manufacture for sale will continue to issue WHO GMP certificate (Only on the request of importing country).**

64. Who will issue the other certificates like Non-Conviction Certificate, Validity Certificate, Market Standing certificate etc. which are not mentioned in rules but are required on request of procurement / tendering agencies?

- **The Licensing Authority who has issued license shall issue such certificates.**

65. Who shall issue Free Sale Certificate of notified regulated medical devices and IVDs?

- **As per Medical Devices Rules, 2017, Central Licensing Authority (CLA) shall issue Free Sale Certificate of notified regulated medical devices and IVDs.**

66. What are the surgical dressings covered under regulations?

- **Surgical dressings including bandages which are intended to be used on wound or injured skin or tissues are covered under regulation.**

66. In the light of New Medical Device Rules 2017, how absorbent cotton will be regulated? Whether as Drug or Medical device and in which class?

- **Absorbent cotton will be regulated as a part of surgical dressings as a Medical Device under Risk class A as per the provisions of Medical Device Rules, 2017.**

67. Whether bandages which do not come in contact with wound or used for providing support/compression are regulated?

- **Bandages which do not come in contact with wound or injured skin or tissue or used for providing support/compression are not covered under the category of surgical dressings.**

68. Whether casting tapes or splints are regulated?

- **Casting tape/Splints intended to be used for external immobilization of fractures/sprains as prescribed by doctor are regulated.**

69. What is regulatory expectation to ensure quality of components (raw materials which are to be used for further manufacturing of finished medical devices including In vitro diagnostic medical devices under the valid licence for manufacturing?

- **With respect to quality of components/raw materials to be used for further manufacturing of finished medical devices under the valid licence for manufacturing, it is required that these components need to qualifying quality standards and Quality Management System (ISO 13485) and, if imported, need to have Free Sale Certificate of their finished product in the GHTF countries. The documentary evidence of the same shall be submitted to the licensing authority (who is issuing manufacturing licence) at**

the time of grant of licence & subsequently, as & when required. Further, it shall also be available for audit/inspection, whenever required.

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Note: Any suggestions with respect to this document may be communicated to this office through e-mail at ddcimd-cdsco@nic.in