**Regulatory Requirements for Medical Devices Including In Vitro Diagnostics in India (Version 2.0)**

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**Lecture – 10**
**Import & export of medical devices and IVDs**

Welcome to Regulatory Requirements for Medical Devices and in Vitro Diagnostics in India lecture 10 that is Import and Export of the medical devices in vitro diagnostic.

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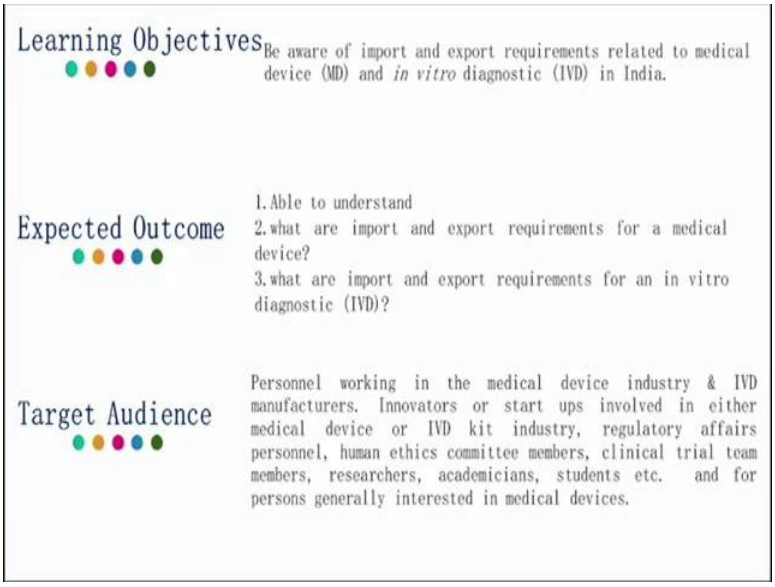


The objective of this lecture to aware the import and export requirement related to the medical devices and in vitro diagnostics in India. The expected outcome of this lecture we will able to understand what are the import and export requirement for the medical devices.

What are the import and export requirements for in vitro diagnostics, target audience, the personnel working in the medical device industry in vitro manufacturers, Innovators or Start ups involved in either medical devices or in vitro diagnostic industry regulatory, Regulatory Affairs Personnels, regulatory affairs personnels, Human Ethics Committee Members, Clinical Trial (CT) team members, Researchers, Academicians, Students and the person generally interested in the medical device field.

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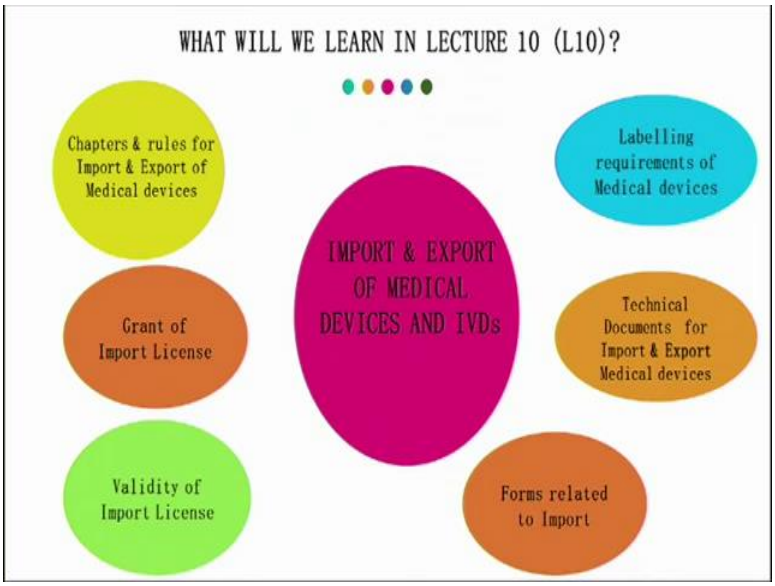


What we will learn in the lecture 10, we will learn the provisions for grant of the import licence, what provision have been given in the medical device rule for grant of the import licence. The forms are related to the import, the import and export of the medical devices and in vitro diagnostics, the chapters and rules related to import and export of the medical devices, validity of the import licence, the labelling requirements for the medical devices, the technical documents for import and export of the medical devices.

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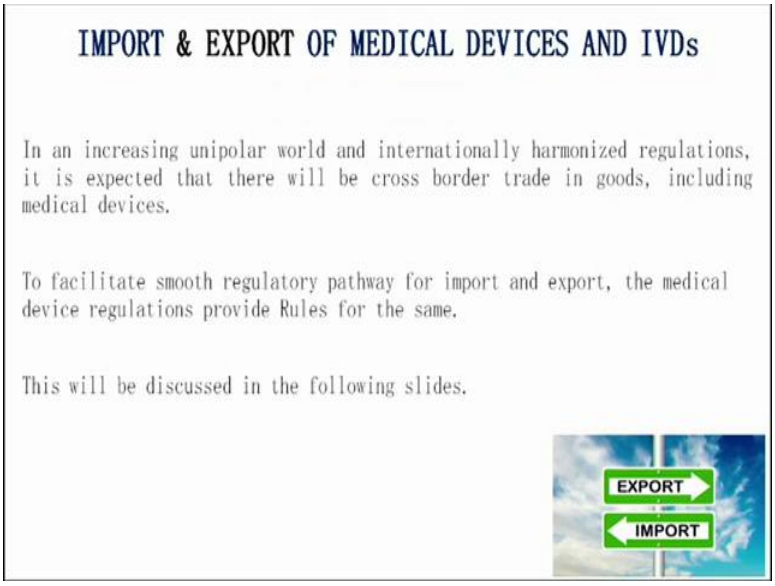

Sothis topic we will discuss and we will cover in this lecture. Now in an increasing unipolar world and internationally harmonized regulation. It is expected that there will be cross border trade in goods including medical devices and to facilitate the smooth regulatory pathway for import and export of the medical devices.

The Ministry of Health and Family Welfare (MoHFW) , Government of India has published the medical device rules for medical device regulations and under the medical device rules the provisions for import and exports of the medical devices and in vitro diagnostic have been provided. Now what are the import provisions which chapters are relates to the imports?

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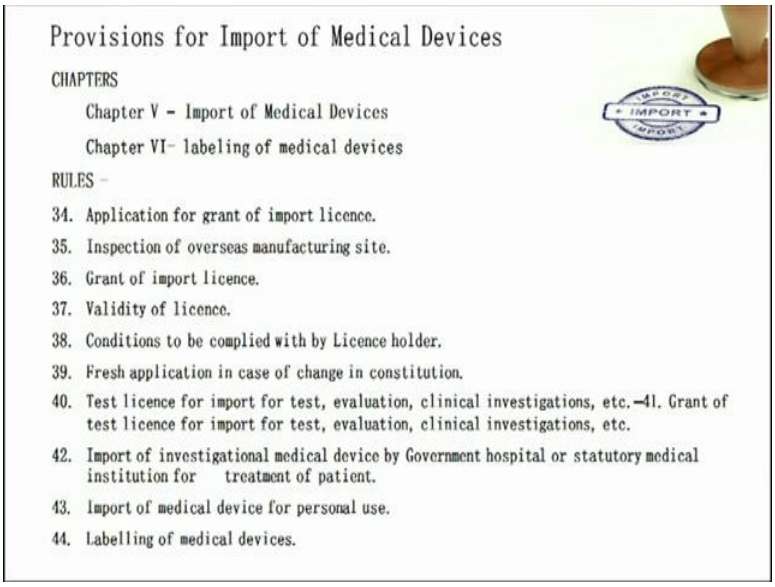


That we will discuss under the Medical Device Rule 2017 in the earlier lectures, we have discuss about the Medical Device Rule(MDR) the detailed discussion on the medical device rule have already been made in the previous lectures. So, under medical device rule we learnt that the chapter 5 deals with the import of the medical devices under chapter 5 the provisions for grant of the import licence, conditions of the licence.

Validity of the licence suspension cancellation of the licence condition to be complied by the licence holders, all those provision have been incorporated in the chapter 5 of the medical device rules. And the labelling of the medical devices the devices which is imported into the country for marketing what are the labeling Provisions. the chapter six of the medical device rules prescribes the labelling requirement.

So, these two chapters that relates to the import of the medical devices and for import, what are the labelling requirement, the importer has to comply with the requirement as prescribed in the medical device rules. The what are the rules related to import of the medical devices under the medical device rules chapter 5 rule 34 to rule 44, these rules covers various provisions of the import licence import of the medical devices. What are those provisions have been made in the rules. Rules 34 under the chapter 5 here the provisions for submission of the application.

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For grant of the import licence have been made the medical devices can be imported into the country, for which the manufacturer should have an authorized agent in the country having a license to manufacture for sale or distribution or wholesale licence. Means the authorized agent who is obtaining the import license from the Central Licensing Authority(CLA) he has authorized agent only if the authorized agent have license to manufacture the medical devices or the authorized agent has valid wholesale license for sale and distribution of medical devices.

Then only he will become the authorized agent of the foreign manufacturers for import of medical devices into the country. The application by the authorized agent shall be made in form 14. That is the application for this form we have also discuss in the Medical Device Rules(MDR) the application that is MD 14 shall be accompanied with the requisite fees which are specified in the second schedule of the medical devices

Medical Device Rules 2017. The fees structure for grant of import licence have been given in the second schedule of the Medical Device Rule 2017.

The application shall be made to the Central Licensing Authority(CLA) through CDSUGAM online portal this is the e-governance solution for the medical devices, we have also discuss this online provision for submission of the application. So, under rule 34 the these this provision have been incorporated the technical document to be submitted at the time of submission of the application by the applicant.

What are the technical document required to be submitted? The documents has been given in the 4th schedule of the Medical Device Rule 2017. The authorized agent we have already that discussed just now. the authorized agent should have valid wholesale license to stock or exhibit for sale and distribution of the medical devices issued under the Drugs and Cosmetic Act and rules 1945 or the authorized agent have manufacturing license to manufacture the medical devices for sale and distribution into the country.

So, the authorized agent shall submit the application to the licensing authority under this rule 34.

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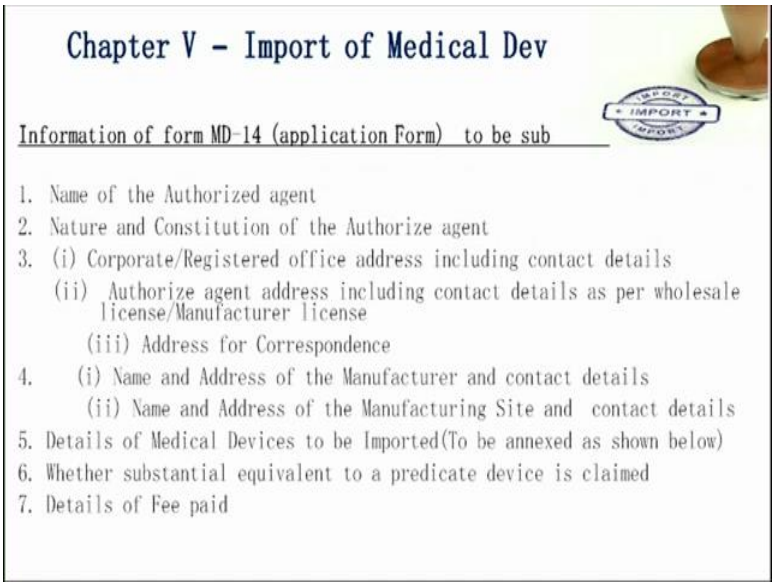


Now, what information has been given, has to be provided in the application form by the applicant the application form that is MD 14. The applicant has to submit the name of the authorized agent. Authorized agent who will be the authorized agent? The manufacturer

has to authorize the agent by through a legal document, that is the Power of attorney and the authorized agents shall submit the application in form 14.

And in form 14 the name of that authorized agent has to be mentioned the nature and constitution of the authorized agent the corporate and registered office of the authorized agent if it is different from the wholesale premises or the manufacturing premises.

The authorized agent address including contact details as mentioned in the wholesale license or the manufacture license , address for the correspondence, the name and address of the manufacturers and contact details; it means the manufacture of the medical devices who have authorized the authorized agent he has to give the name and address of their site. Name and address of the actual manufacturing site where the manufacture where the medical devices or in vitro diagnostic are manufactured the contact details of the that site, details of the medical devices to be imported the details is given in the next slide.

If there is a substantial equivalent device to a predicate devices if it is clean the details of that devices has to be given, the details of the fees, the fees has mentioned in the second schedule of the Medical Device Rule 2017 the applicant has to submit that fees.

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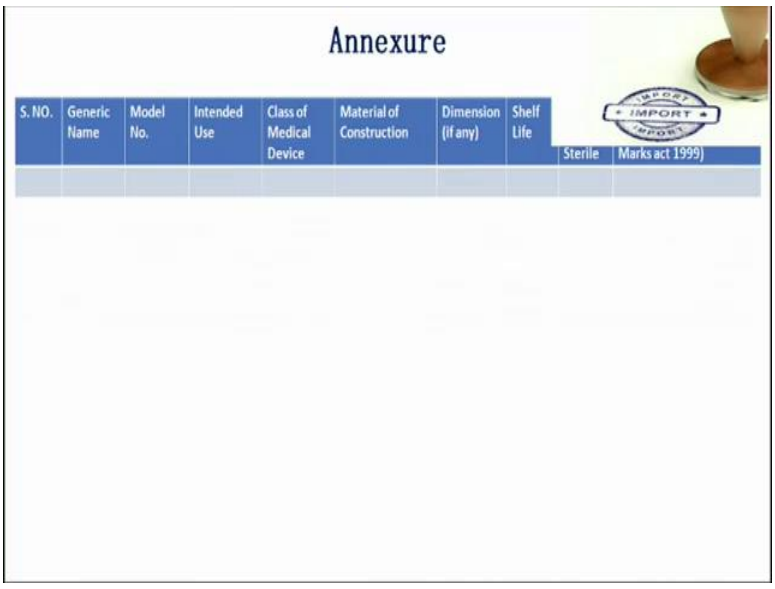


Now the information of the devices which is required to be mentioned in the application, the generic name of the devices, modern name of the devices, intended use, class of the

medical devices, material of construction, dimensions, shelf life of the devices, sterile or non sterile, if there is a branding all those information that has to be mentioned in the application.

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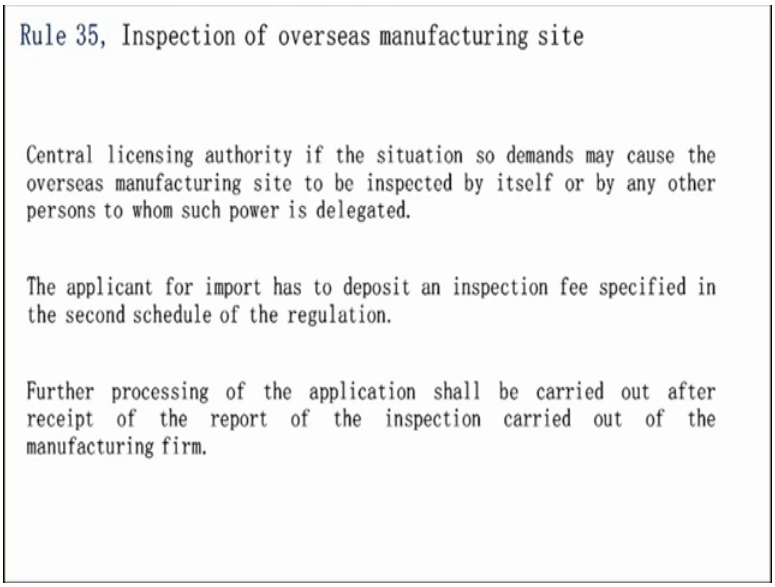


Now, rule 35 that is the provision for inspection of the overseas manufacturing site the Central Licensing Authority(CLA) if the situation. So, demand may cause the overseas manufacturing site to be inspected by itself or by any other person to whom such power is delegated. The applicant for import has to deposit inspection fees has a specified in the second schedule of the regulation, the inspection fees of US dollar 6000, that has been made in the second schedule that fees has to be submitted by the applicant. And further processing of the applications shall be carried out after receipt of the report of the inspection carried out by the Central Licensing Authority(CLA) at the manufacturing premise.

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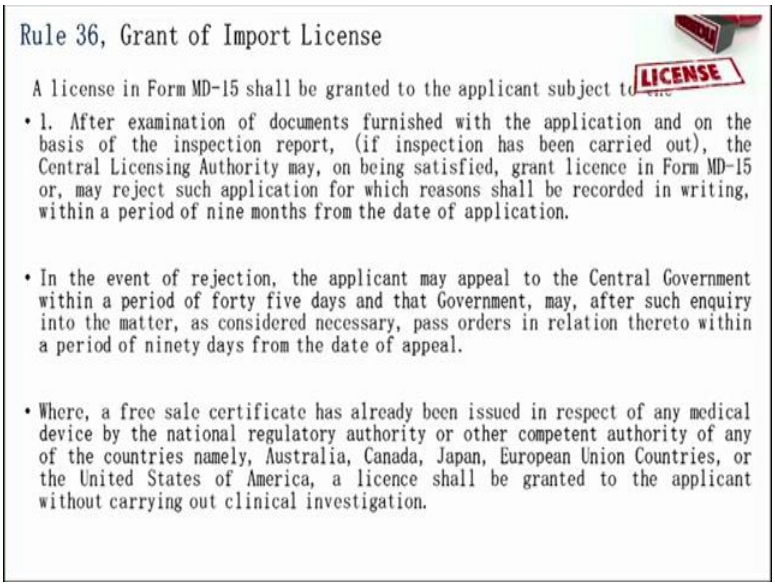


Now, Rule 36 that is grant of the import license a license in form 15 shall be granted to the applicant or subject to the condition that after examination of the document furnished by the applicant and this inspection report of the manufacturing premises, if the inspection is carried out. The licensing authority may review and after being satisfied the requirement grant the license in form MD 15 to the applicant for import of the medical devices or he may reject the application for which reasons shall be recorded in writing within a period of 9 month from the date of the application.

So, if the documents submitted by the applicant found satisfactory the licensing authority will grant the import license, if it is not satisfied, the documents are not satisfied he may reject the application and the reason for rejection of the application has to be recorded within the period of 9 month from the date of submission of the application. In the event of rejection if the application is rejected by the Central Licensing Authority(CLA) the applicant may appeal to the central government that is the Ministry of Health and Family Welfare(MoHFW) within a period of 45 days and that Government may after such enquiry into the matter has consider necessary pass and order in relation there are to within a period of 90 days from the date of appeal.

So, the applicant has to appeal to the Central Government that is the Ministry in case of rejection of the their application where the fees and certificate has already issued in respect of the medical devices, which is to be imported by the National Regulatory

Authority of the countries that is Australia, Canada, Japan, European Union, United State of America, license shall be granted to the applicant without carry out clinical investigation. It means if the product or the devices which is to be imported is approved by the National Regulatory Authority (NRA) of these country that is Australia the authorities DGA Canada health Canada, Japan PMDA European Union, USA that is US of FDA.

If this authority have approved the particular devices, which is to be imported in such cases there is a no requirement of the clinical investigation and based on the document and fees submitted by the application and if it is found satisfactory the import license shall be issued by the Central Licensing Authority (CLA)

Rule 36 grant of import license, that is continue where the medical devices is imported from the country.

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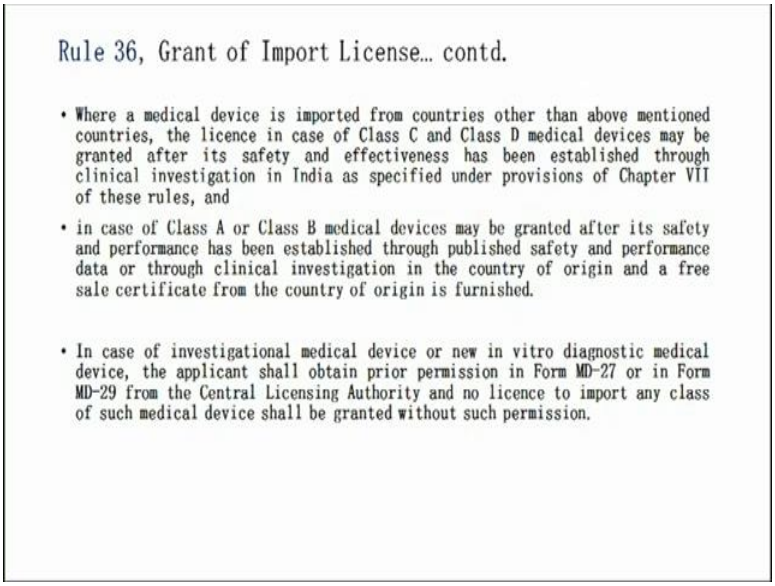


Other than above 5 countries which we have just discussed, the license in case of Class C and Class D medical devices. May be granted only after its safety and effectiveness has been established through the clinical investigation in India as specified under the provision of chapter 7 of this rule.

And for class A medical device, Class A and class B devices medical devices the safety and performance has to be established through the published safety and performance data

or through the clinical investigation in the country of origin and the free sale certificate from the country of origin is required to be submitted. In case of the Investigational Medical Devices or new in vitro diagnostic medical devices the applicant shall obtain prior a permission in form MD 27 or in form MD 29 from the Central Licensing Authority(CLA) and no license to import any class of such medical devices shall be granted without such permission.

So, if the devices or the in vitro diagnostic kit which does not have the predicate devices it is imported into the country the applicant has to obtain prior permission from the Central Licensing Authority(CLA) and in form MD 27 or form MD 29. And then they have to apply for the import license for import of the devices into the country.

Rule 37, that is validity of the license the license issued by the Central Licensing Authority(CLA) in MD 15 does not have the date of expiry and it is perpetual.

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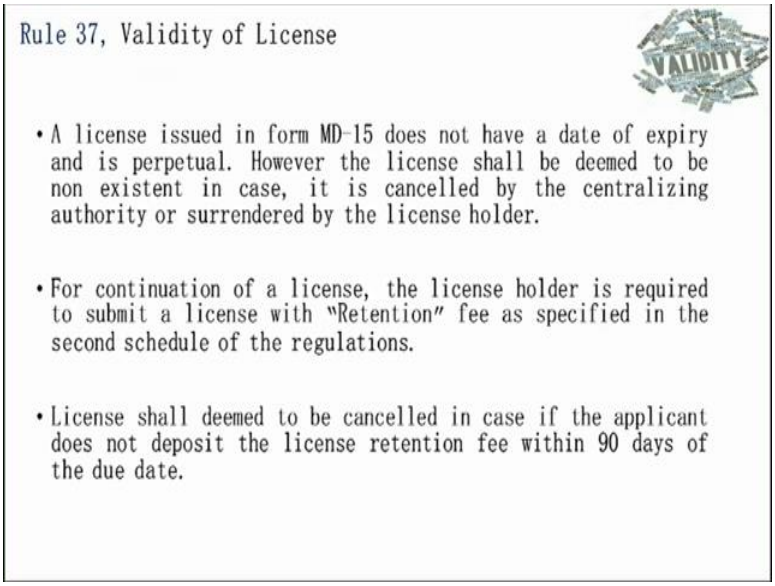


However the license shall deemed to be nonexistent in case it is cancelled by the Central Licensing Authority or surrendered by the license holder.

So, the license in MD 15 issued by the Central Licensing Authority is in perpetual till it is cancelled or suspended by the Central Licensing Authority or withdrawn by the license holder. However, for continuation of the license the license holder is required to submit requisite retention fees as specified in the second schedule of the medical device rule

2017, the license the license shall deemed to be cancelled in case if the applicant does not deposit retention fees within a period of 90 days from the due date.

So, this provision have been made in the rule 37 and if the applicant or the importer comply with this requirement there license will be valid.

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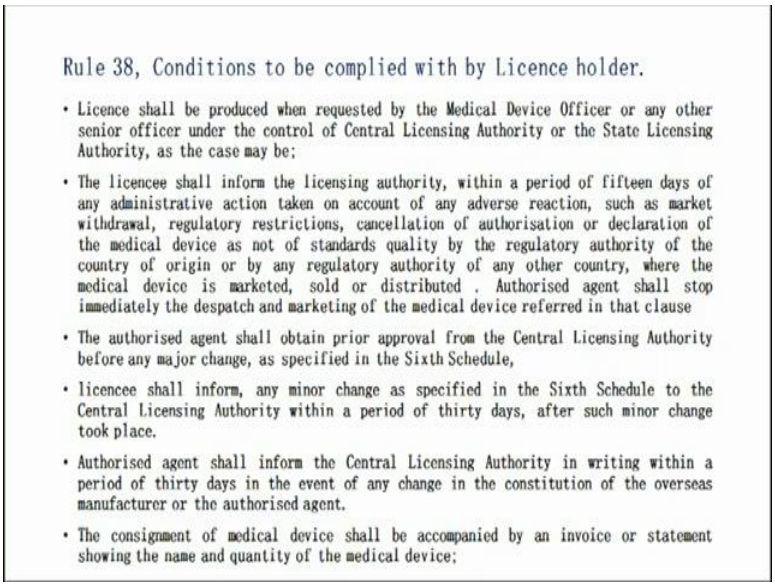


In perpetual Rule 38 that is the conditions to be complied by the license holder, once the license is granted the conditions of the license has been prescribed and the licensee has to restrict with the requirement as a part of the condition of the license. The license holder has to produce license when the request by the Medical Device Officer(MDO) or any other senior officers under the control of Central Licensing Authority(CLA) or the State Licensing Authority(SLA) has the case may be.

So, he has to produce whenever that central licensing authority or the state licensing authority ask for the license the licensee shall inform the licensing authority within a period of 15 days of any administration action taken on account of any Adverse Event(AE). such as market withdrawal regulatory restrictions ,cancellations of the authorization or declaration of the medical devices as not of the standard quality by regulatory authority of country of origin or any regulatory authority of any other country.

Where the medical device is marketed sold or distributed the authorized agent shall stop immediately the dispatch and marketing of the medical devices referred in that clause.

Authorized agent shall obtain prior approval from the Central Licensing Authority before any major changes as specified in the sixth schedule, the licensee shall inform any minor changes as specified in the sixth schedule to the central licensing authority within a period of 30 days.

after such minor changes took place authorized agents shall inform central licensing authority in drafting within a period of 30 days in the event of any change in the constitution of the authorized agent or the constitution of the overseas manufactures also, the consignment which is to be imported shall accompanied by an invoice or the statement showing the name and quantity of the medical devices.

So, these are the conditions of the import license which has to comply with the complied by the license holder

Rule 39 the fresh application in case of the change in the constitution.

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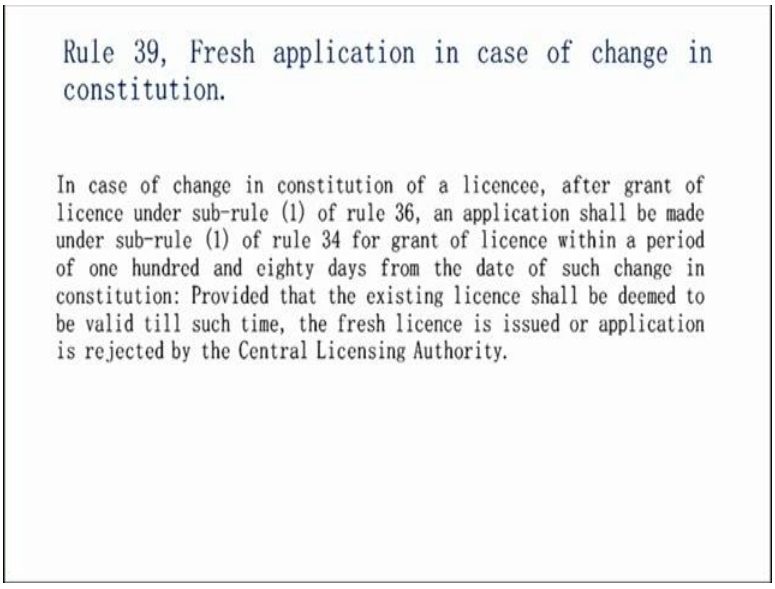


We have already discussed that if there is a change in the constitution of the authorized agent or the foreign manufacturers, that will consider as a major changes and prior approval is required and the license holder has to submit fresh application for grant of the import license for the same rule 40 that provision for import of the medical devices for the purpose of test evolution and clinical investigation.

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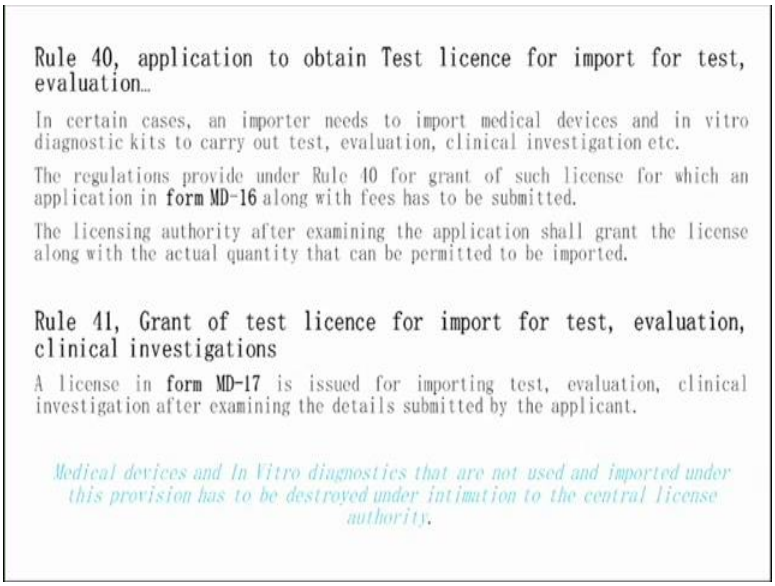


So, in certain cases importer need to import medical devices or in vitro diagnostic kits for the purpose of test evolution of clinical investigation or even demonstration purpose the applicant has to submit application to the Central Licensing Authority (CLA) in MD 16 along with the fees and licensing authority after examining the application shall grant the license along with the actual quantity that can be permitted to the imported.

So, Rule 14 is the mode of application submitted to the Central Licensing Authority for the purpose of import of medical devices, for test are evaluation of clinical investigation purpose and Rule 41 the provision for grant of such test licence for import of medical devices for test and evaluation clinical investigation have been issued in form 17.

There the medical devices or in vitro diagnostics imported for this purpose that are not used the unused quantity of the medical devices or in vitro diagnostics has to be destroyed under intimation to the Central Licensing Authority, that product which is unused cannot be used for any other purpose and the importer has to destroy all such unused quantity with a intimation to the Central Licensing Authority.

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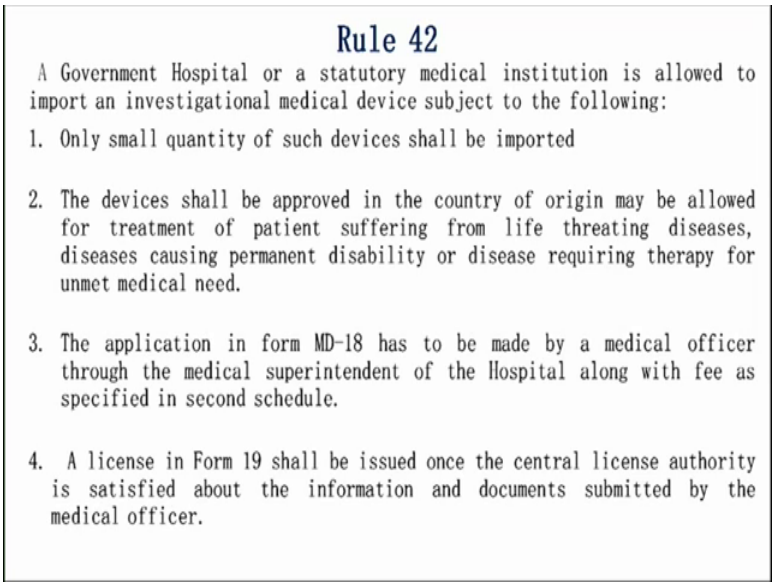


Rule 42 the Provision for government hospital or the statutory medical institution is allowed to import an investigational medical devices subject to the following. Only small quantity of such devices shall be imported. the device shall be approved in the country of origin may be allowed for the treatment of the patient suffering from life threatening disease.

The application in MD 18 has to be made by the medical officer through the medical superintendent of the hospital along with the fees as a specified in the second schedule license in form 19 shall be issued once the Central Licensing Authority is satisfied about the information and documents submitted by the medical devices.

Medical officers of the hospital it means if the investigational medical devices or the new in vitro diagnostics, which is not approved for marketing into the country and if the hospital, government hospital or the statutory medical institution required to import that investigation medical devices Which is approved in the country of origin where the product is importing he can obtain the permission for the treatment of their patient under the license in form 19.

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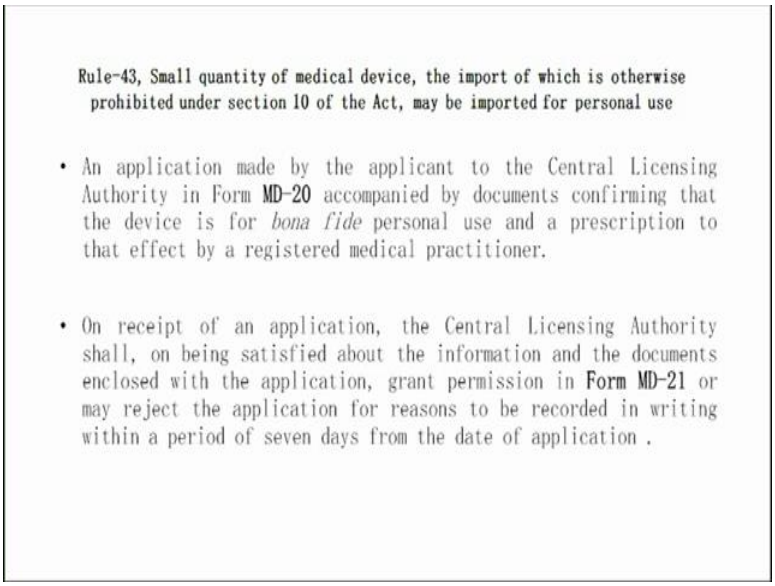


The Rule 43 here the provision for small quantity of the medical devices for import of which is otherwise prohibited under the section 10 of the act, may be imported for personal use the patient can import the such devices based on the prescription of the Registered Medical Practitioner (RMP).

The applicant has to submit the application to the Central Licensing Authority in form MD 20 accompanied by the document confirming the device is for the bona fide personal use and the prescription to the e registered medical practitioners. on receipt of the application central licensing authority after being satisfied, the document submitted by the applicant they shall grant the permission in MD 21 or he may reject the application for the reason to be recorded in writing within a period of 7 days from the date of application.

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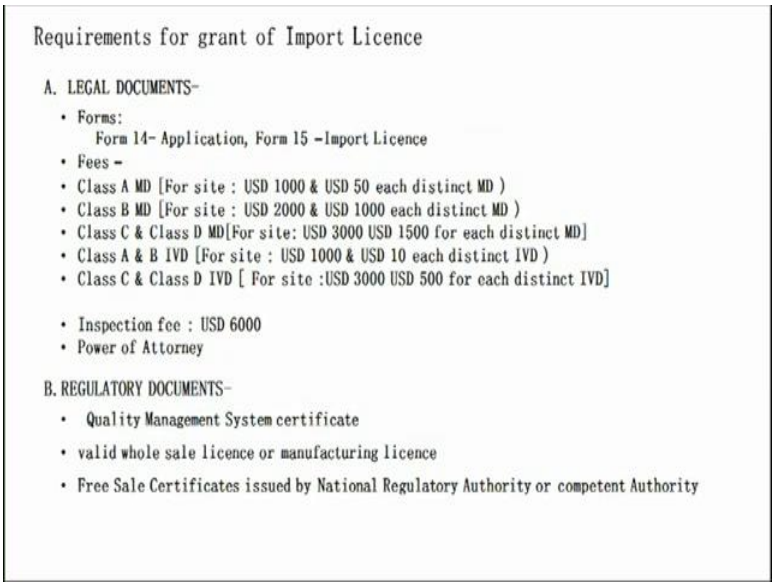


Now, the requirement for the grant of import license. we have discussed what are the rules related to the import of the medical devices and in vitro diagnostics. Now for obtaining the import license, what are the requirement that we will discuss in this slides the legal document in the rules. We have discussed which form is required form 14 is the application and form 15 after being satisfied with the document, which we have discussed in the previous slides, licensing authority shall grant licensing form 15.

The fees, the fees structure for different class of the medical devices and in vitro diagnostic kits different fees structure is given for class A medical devices u s dollar 1000 and US dollar 50 is distinct medical devices for class B medical devices for the side 2000 US dollar for the each distinct medical devices 1000 US dollar.

Class C and class D medical devices for the for the side US dollar 3000 and for each distinct medical devices US dollar 1500 for class A class B medical in vitro diagnostic kits for side 1000 US dollar and for each distinct IVDs 10 US dollar for class C and class D IVDs, for the side 3000 US dollar and US dollar 500 for each distinct in vitro diagnostics also if in case of the inspection of the foreign manufacturing site the applicant has to submit US dollar of 6000 as a inspection fee for the foreign manufacturing site the power of attorney

That is the legal document the part 1 of the fourth schedule have the format for the power of attorney that power of attorney has to be attested from the first class Gazetted Officer

or the Indian Embassy from the country of origin. Through that power of attorney the foreign manufacturers is given all the responsibility to the authorized agent for import and marketing of their product into the Indian market, the legal documents these are the legal documents and the regulatory certificates what are the regulatory certificates required to be submitted the Quality Management system certificate all the ISO certificates with respect to the facility with respect to the product applied the applicant has to submit.

That the whole copy of the wholesale license of the authorized agent or the manufacturing license of the authorized agent the free sale certificate issued by the National Regulatory Authority(NRA) or the competent authority from the country of origin and also from the 5 major countries of the that is USA, Australia, Japan, Canada, European union.

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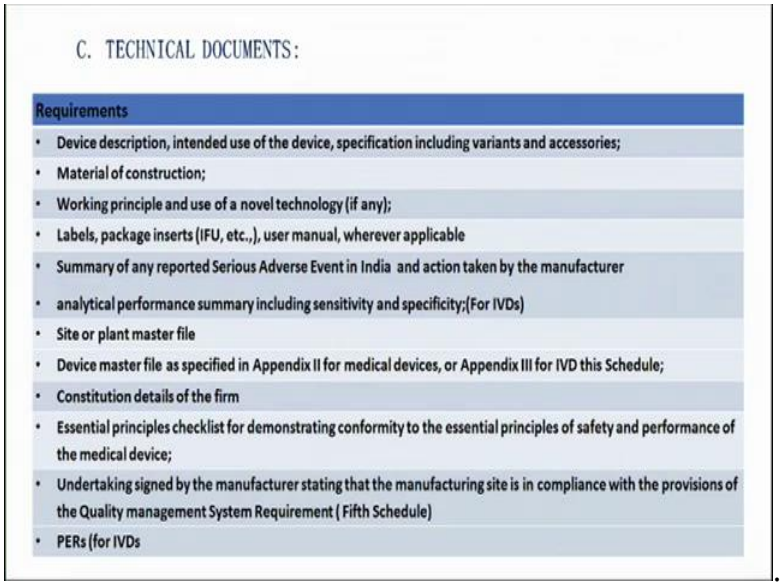


The technical documents the requirement of the technical documents is also given in the part 2 of the fourth schedule of medical device rule 2017. We have discuss in that lecture, now what are the technical documents briefly. We will discuss again here the device description intended use of the device specification including variant and accessories of the medical devices, material of construction, working principles and used of the novel technology, if any, labelling packaging package inserts users need wherever applicable.

The summary of any reported Serious Adverse Event(SAE) in India and the action taken by the manufacturers in case of the in vitro diagnostic kits analytical performance summary the including the sensitivity and specificity Site Master File(SMF) of the foreign manufacturing site Device Master File(DMF) as a specified in appendix 2 for the medical devices or the device master file as specified in the appendix 3 of the of the fourth schedule of the medical device rules. constitution details of the firm both authorized agents and foreign manufacturers their constitution details has to be submitted.

The essential principle checklist for demonstrating conformity to the essential principle of safety and performance of the medical devices, undertaking signed by the manufacturer stating that their facility is in compliance to the provisions of quality management requirement as a specified in fifth schedule of medical device rule 2017, the performance evaluation report for in vitro diagnostic kits. So, these are the details of the technical documents that required to be submitted the details of the Plant Master File(PMF) and device master file is clearly given in the fourth schedule.

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The requirement for the import license, we have also discussed that timeline 9 month timeline has been given in the medical device rule for grant of the import license the validity of the license, this license issued by the Central Licensing Authority is valid in

perpetuity unless it is suspended or cancelled or surrendered also we have discussed in case of investigation medical devices or in new in vitro diagnostic kits,.

the applicant shall submit an application in MD 26 for investigational medical devices or MD 28 for new in vitro diagnostic and obtain prior permission from the Central Licensing Authority in form 27 for medical devices and in form MD 29 for in vitro diagnostics and submit the same to the licensing authority for obtaining the import license for marketing into the country.

Where fresh application is required to be submitted by the importer in case of change in the constitution of the firm, constitution of the authorized agent or foreign manufacturing site.

And also we have discuss that all this application shall be made to the Central Licensing Authority through online central portal that is CDSCOMDONLINE.COM and through that online system, there is a checklist for submission of all these documents each document has to be uploaded by the applicant at the time of submission of the application. the application is reviewed through online portal and also the license will be issued by the Central Licensing Authority through that central online portal for import of the medical devices the import license for test and evolution demonstration purpose.

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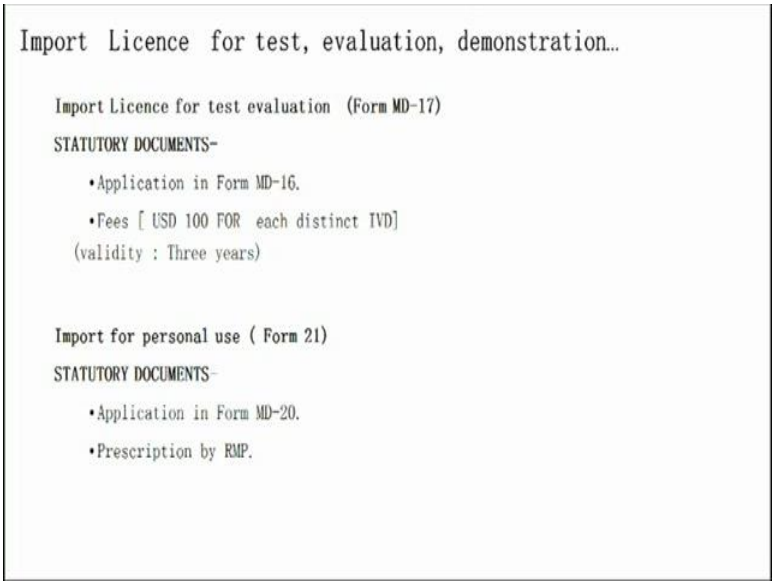

We have already discussed that application in form MD 16 along with the fees of US dollar 100 for each distinct in vitro diagnostic product or devices and the license is issued for the 3 years.

Import for personal use that is the permission issued by the Central Licensing Authority to the patient for the personal use, they have to submit the application to the central licensing authority in MD 20 along with the prescription from the registered medical practitioner and based on the satisfactory documents submitted by the applicant the permission is granted by the central licensing authority.

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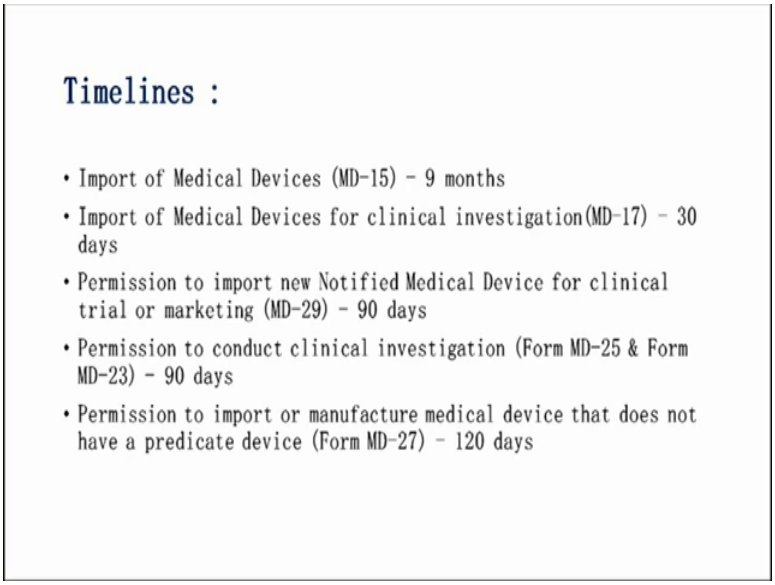


Different timeline for different import activity has been given in the medical device rule 2017 for import license 9 month. We have already discussed that import of the medical devices for the clinical investigation purpose 30 days timeline has been given for grant of such license permission to import new in vitro diagnostics kits for investigational medical devices. 90 days timeline has been given. Permission to import or manufacture medical devices that does not have the predicate devices 120 days timeline has been given.

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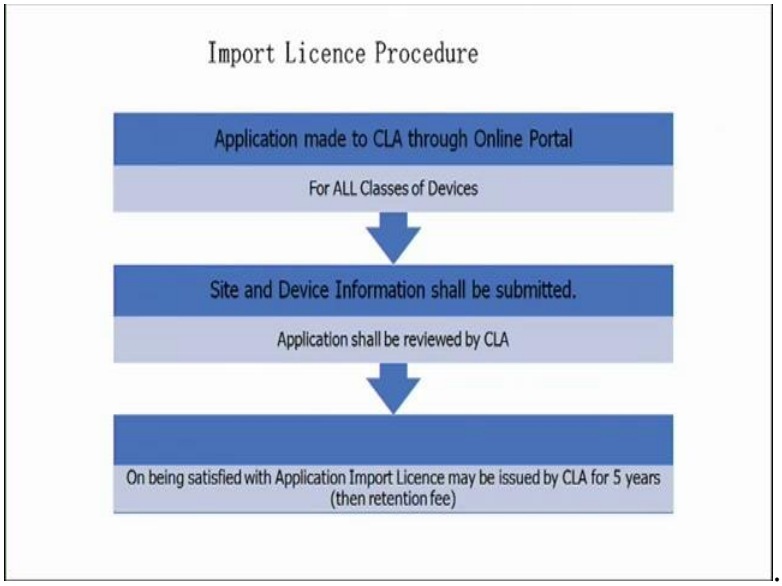


So, different activity different timeline has been given in the medical device rule 2017. Now this is the procedure that has to be followed for obtaining the import license, we have already discussed that application shall be made to the Central Licensing Authority through online portal for all classes of the devices the requisite document, then fees that has to be submitted by the applicant to the central licensing authority through the online portal in case if there is inspection of the overseasmanufacturing premises. Their application will be considered only after satisfactory submission of the inspection report and the document as required under the provisions of medical device rule 2017.

The application is reviewed through online in also on being satisfied license is issued by the Central Licensing Authority for a period of 5 years. However, this license is issued in perpetual provided a retention fees as prescribed in the second schedule of the medical device rule 2017 has to be submitted by the applicant, now come to the export of the medical devices.

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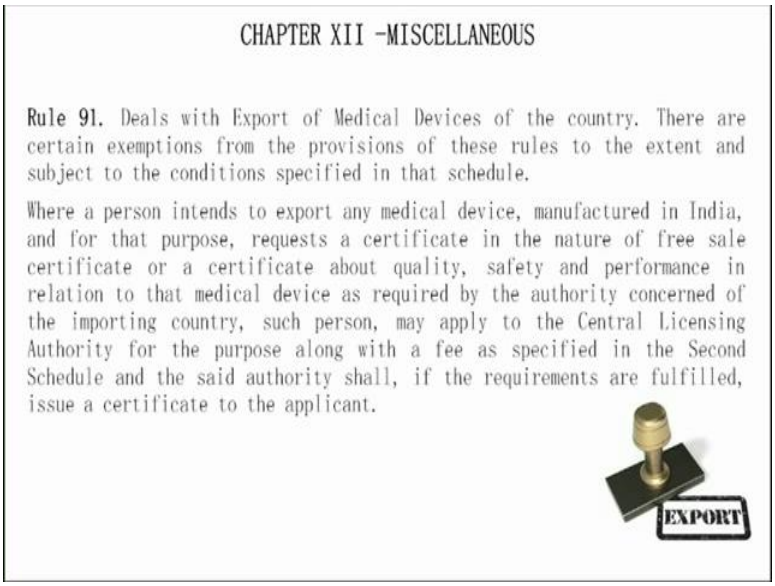


In the Drugs and cosmetic rules 2000:1945, there is there were no any that provision for the export of the medical devices in this medical device rule under chapter 12. That is the miscellaneous chapters Rule 91 has been provided which deals with the export of the medical devices in the country.

There is a certain exemptions from the provision of these rules to the extent and subject to the condition specified in that schedule. the person intend to export any medical devices manufacturing in the country and for that purpose requests A free sale certificate from the central licensing authority about the quality safety and performance in relation to that medical devices as required by the authority concerned of the importing country and such person may apply to the Central Licensing Authority along with the fees as specified in the second schedule and the Central Licensing Authority after examine examination of their application and based on the approval given to the applicant.

The licensing authority shall issue the free sale certificate for the purpose of export of that particular medical devices or in vitro diagnostics.

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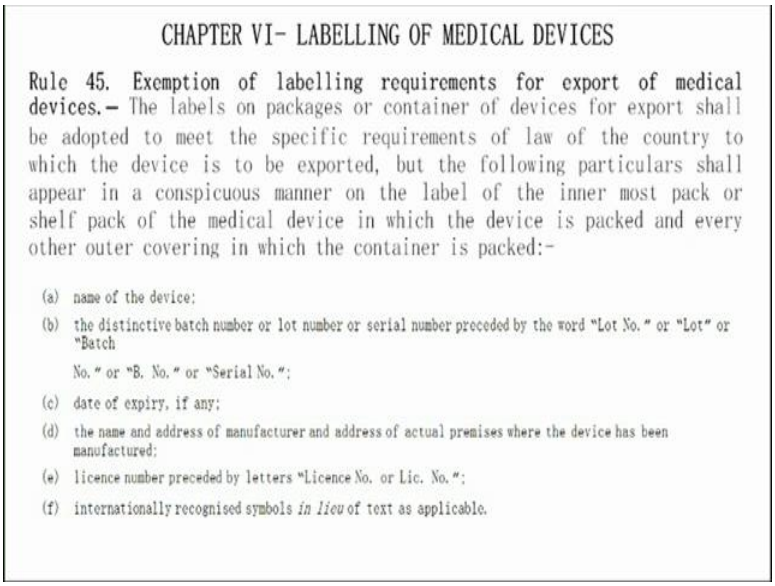


Also in the chapter 6 of the medical device rule 2007The exemptions labelling requirement for the export of the medical devices has been given the labelling requirement, but applicable for the export only certain information that applicant, that the exporter has to be mentioned on the label of the product which is to be exported.

And that information that name of the devices distinct batch number of the devices expiry, date of expiry if any the name and address of the manufacturers and address of the actual premises. Where the device is manufactured license number and the internationally recognized symbol as applicable only that much information that has to be mentioned on the label of the product which is to be exported. So, these 2 provisions have been given for the export of the medical devices.

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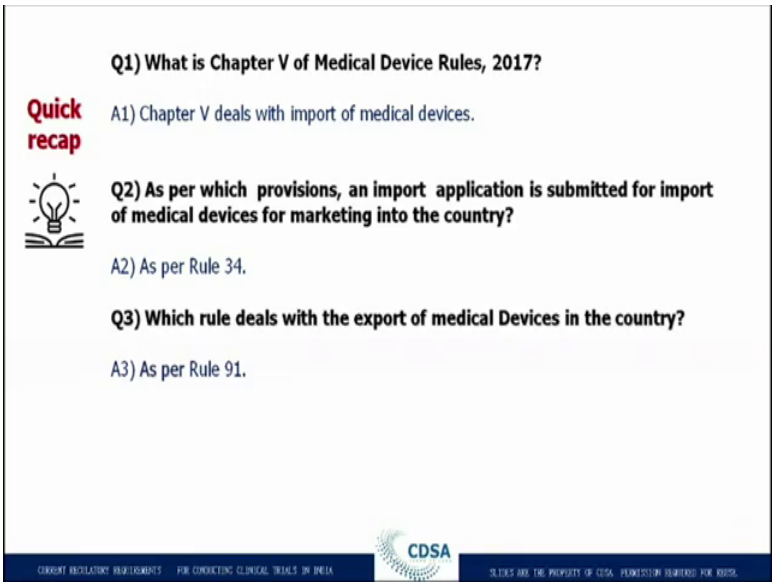


So, by this way we have completed this chapter let us have some question answer session.

So, we have discussed about the import requirement for the medical devices and in vitro diagnostics. What are the export requirement made in the medical device rules for medical devices and in vitro diagnostics. So, can you tell me which chapter that medical device rule 2017 deals with the import of the medical devices or other way around.

What is the chapter 4 of the medical device rule 2017? Chapter 5 what is chapter 5 of the medical device rule 2017?

Chapter 5 is a chapter which deals with the import of the medical devices.

Now question 2 as per which provisions and import application is submitted for import of medical devices for marketing into the country.

What is the answer the answer as per Rule 34 which rules deals with the export of the medical devices in the country, yeah its Rule 91of the medical device rule 2017. So, friends with this we have completed all the chapters of the medical device regulations and you will have overall idea about the regulation of the medical device in the country you have understand, what is the requirement for the import? What is requirement for the manufacture of the medical devices and in vitro diagnostic? What is the Quality Management System(QMS)? What is the classification criteria of the medical devices?

What is the standards applicable for the medical devices? What is the import requirement for the medical devices? So, with this we have almost completed the course on the medical device regulation and for further details you can visit the site of the Central Licensing Authority(CLA), that is CDSCO where details of the medical device rules various guidance published by the central licensing authority details of the classification list guidance on the essential principles guidance on the grouping of the medical devices all those information is available you have to go through that website,.you have to go to that in documents in details and if you have any clarification of further doubt you can approach to the CDSCO for further clarification and with this words, I would like to close my this lectures and also I will give my best wishes to you because you will be ready for the online examination all the best.

Thank you.