REGULATIONS OF REGISTRATION AND IMPORT OF MEDICAL DEVICE IN INDIA

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REVIEW ARTICLE

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ABSTRACT

India is a huge market for medical devices and is increasing constantly for the last few years. The registration certificate and import license is mandatory for a manufacturer of India who wishes to import any medical device in India. If a company which wants to imports its medical devices in India does not have a registered office in India it needs Indian agent authorized by CDSCO, to do so. Duly filled form-10 is required to be submitted for import license, while form-44 duly filled is required to be submitted for marketing authorization of a new medical device or its re-registration. The review focuses on regulation concerned to the registration procedures import of a new medical device in India with latest amendments in the regulation concerned.

Keywords: Medical devices, Regulation, Import, Registration.

INTRODUCTION

India attracts the manufacturer all over the world for import owning to its large population and therefore has a capacity to be the world largest market in present scenario. India, Central Drug Standard Controlled Organization (CDSCO) currently regulates the medical devices, which is a part of Ministry of health and family welfare. All the actions which are related to medical devices such as their import, manufacturing, sale, distribution and export are governed by the Drug and Cosmetic act 1940 and Rules 1945. Drug and Cosmetic (amendment) Bill 2013 contains the latest amendment concerned to the same. This act also includes a separate chapter for import and registration procedure of medical devices. (1, 2)

According to the latest Indian guidelines the products which are already approved in Indian market need no additional legal formality for being registered for import. India is a major business opportunity for the investment community because India is a large market of healthcare products and it is growing day by day. Foreign medical equipment companies are trying their healthcare products to import in India (3). Since, India is a price sensitive market, cheap and low priced medical devices also have a good market. Notified medical devices which are already approved in United States (US) and European Union (EU) are allowed in Indian market. These products do not require other conformity assessment procedures in India. These products are highly preferred due to their quality and better performance. (4,5)

Registration Procedure

For the import of medical devices in India, registration and import license is mandatory. So, a person willing to import medical product in India, he must have to obtain registration certificate and import license. A person wishing to obtain a import license have to make application for registration in the given time period (60 days from the date of implementing of these guidelines). In case, before the date of notification, devices have not been imported in the country, import is not allowed. For import of medical device in India, approval of competent authority is required. In a certain time period, until an application is rejected or approved, those devices which are currently in use are allowed in the market.

There are many products in India which require registration including spinal needles, heart valve, annuloplasty rings, syringes and needles, cochlear implants, cardiac stents, catheters etc. Any company, willing to legally register or import medical devices in India, needs to comply with the rules as per Drugs and cosmetic act 1940 and rule 1945 regulations by CDSCO (6). In case, company has not a registered office in India, company has to hire a "authorized agent" to manage registration and other related processes. An "authorized agent" may be defined as any person in India and authorized by manufacturer. An "authorized agent" plays very important role in registration procedure and responsible for following actions (6):

1. Business activity
2. Post-market surveillance
3. Pre-certification.

Import procedure of Medical Devices in India

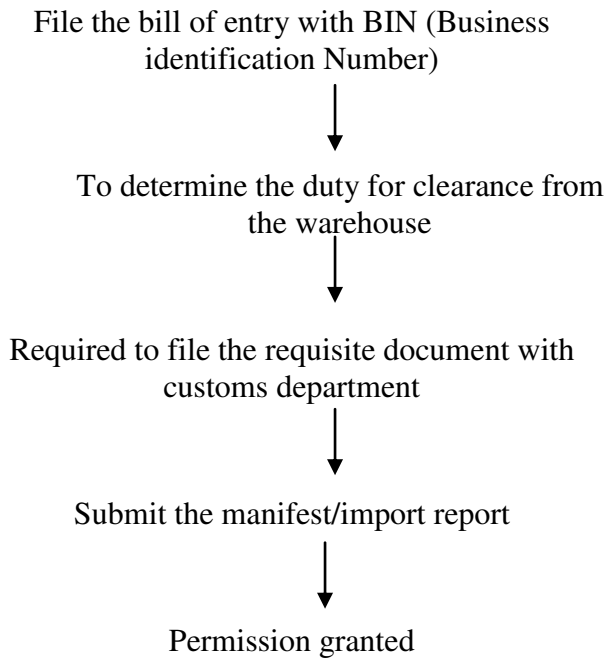

Figure 1: Import procedure of Medical Devices in India

Form 41:

Registration certificate is issued under rule 27 by licensing authority for registration of premises and drugs which are meant for import. Import license (Form 10) and registration certificate (Form 41) is needed for marketing of imported medical devices under Drug and Cosmetic act and rules in India. Registration certificate is obtained from the licensing authority. A number of documents are required to be submitted with the Form 41 which are listed below (7):

1. In Form-40
2. TR-6 Challan application
3. Schedule DI
4. Schedule DII
5. Power of attorney
6. Free sale certificate
7. Valid wholesale license/ manufacturing license
8. Copies of quality certification
9. Device master file
10. Plant master file
11. FU and Pack insets of devices
12. Device label

(Form 44) Re-Registration

Rule 24A, 25B, 27A, and 28A of Drug and Cosmetic rules contains descriptive information about requirements for grant of registration certificate. For the re-registration, the process is same as for the registration for medical devices. A copy of registration certificate is required to be submitted along with application which should be in form 41. In this application following information must be mentioned (8):

1. Intent of application
2. If the application is submitted for the first time
3. whether the application is for re-registration
4. For endorsement of additional product.

Form 10:

This form is duly filled form 10 A and to obtain the license for schedule X drugs in the drugs and cosmetic act 1940 and rules 1945. Import license is a license to allow the import of drugs excluding which are specified in schedule X. It is a license in Form 10 A to allow the importation of drugs which are specified in schedule X. Following medical devices are regulated currently (9):

1. Disposable perfusion sets
2. disposable hypodermic needles

3. disposable hypodermis syringes
4. catheters
5. cardiac stents
6. bone cements
7. in -vitro diagnosis devices for HIV, HCV
8. scalp vein set
9. heart valve
10. v. cannulae
11. orthopaedic implants
12. Drug eluting stents etc.

For import of medical devices, a list of documents is needed to be submitted with Form 10.These documents are as (10):

1. Form -8 duly signed and stamped by application
2. Form-9
3. copy of wholesale license/ manufacturing license
4. TR-challan
5. copy of registration certificate in form 41
6. Label.

Process of Registration of Medical Devices

Distributor can apply directly to CDSCO in Form 10 for import

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Application can be made in Form 8 along with Form 9 that provides registration certificate number

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Processing of application may take 4 -12 weeks. If all required information is in order, then license will be issued in Form 10 within three months and it is valid for three years unless it is cancelled or suspended.

Figure 2: Process of Registration of Medical Devices

Process of application for obtaining Import License which does not require fresh Registration:

According to CDSCO, only notification /amendment may be obtained in these cases. A fresh application with power of attorney incorporating need to be submitted in two cases (11):

1. Change in indication
2. Change in intended use.

Marketing authorization of new medical devices (form 44 and form 45):

If a company wants to import new medical devices in India, it requires the permission from DCGI by filling an application. Application must be in form 44.With the application, data given in schedule Y of Drug and Cosmetic act 1940 and rules 1945 must be submitted. This includes result of local clinical trial which is carried out properly according to the guidelines. The applicant must provide authentic and satisfactory market data and clinical studies conducted worldwide. (10) Safety data is obtained to get registration certificate. Information required for filling form 44 as listed below (11):

1. Generic and brand name
2. Composition, specification and standards of device
3. Qualitative and quantitative particulars of constituents
4. labeling details
5. sterility and stability information of product
6. variation in shape/style/size
7. list of devices to be used in conjugation
8. packaging description including pack size
9. risk classification ,in country of origin and five GHTF countries
10. indication for which the devise is sought to be in market
11. physician, manual and promotional literature in English
12. Name, address of manufacturer.

After being satisfied, the licensing authority may grant permission for import which is in form 45.Whole process may take six months .In case the data is inadequate authority can withhold the permission.

Latest Amendments for Import of Medical Devices:

In 2016, the union health ministry of INDIA published a new draft for medical devices including regulations for import of medical devices which are listed below (12):

1. All powers to grant import license and all related functions are performed by central licensing authority. Specified in sub rule 1 and 2 of rule 5.

2. A person wishing to obtain import license require to make an application to central licensing authority in Form 12.

3. Fee specified in second schedule along the documents which are specified in part1, 2, 3 of first schedule, required to be submitted. If there is any change in the documents at the time of submission of application, central licensing authority must to be notified about it.

4. If the same manufacturers apply for grant of license of additional manufacturing site, he need to submit a fee specified in sub rule 3.

5. If the same manufacturers apply for grant of license of additional medical devices he needs to submit a fee specified in second rule for each devices.

6. If same manufacturer apply for grant of license of different variants of already registered product then the additional fee must be paid for each variant.

7. If authority has doubt related to the quality of devices, then it requires evaluation of that devices and fee charged by testing centre for the examination, test or evaluation is paid by authorized agent.

8. If the license is damaged, defected or lost, authorized agent need to make an application with specified fee under the second rule for duplicate copy.

9. Inspection can be done by central licensing authority or other person to whom the power is delegated and applicant is liable to pay the required fee (second rule) in respect of expenditure required.

10. Issuing of license: Small quality medical devices, import of these devices is not allowed, but approved in the country of origin can be allowed by central licensing authority .Application can be made by medical officer or a statutory medical institution in Form 16. Grant of import license for these medical devices is issued in Form MD 17.

11. The import of some small quantity of medical devices is not allowed but can be imported for personal use and application is made in Form 18. Permission is granted in Form 19.

12. Import of In vitro diagnostic medical devices is not allowed usually, but can be allowed for the purpose of clinical investigation, test, demonstration, evaluation and training.

13. License is required to be made available in the premise which is licensed.

14. When central licensing authority satisfied about the information, data and documents with the application license is granted in Form 13.

15. If the medical devices have obtained free sale certificate from the regulatory authority of United State, European Union, Canada, Australia and Japan. License is granted under sub rule 1.

16. If the devices is imported from countries other than those specified in sub rule 2 ,license for the class C and class D medical devices is issuing after safety and effectiveness check and Clinical investigation can also be required in India under part 7 of these rules.

CONCLUSION

The import of medical devices in India requires a regulatory framework which is a mandate .This not only helps in a hastle free import of medical devices in the country but also to keep a check on quality of imported medical devices in the country.

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CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

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