Regulatory Issues is More Import of Pharmaceutical Products in India

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ABSTRACT :
The value of the global pharmaceutical market is expected to grow at 5 percent CAGR, to be USD 1 trillion in 2014 according to Urch publishing. The pharmaceutical industry is one of the highly regulated industries, to protect the health and well-being of the public. In the present scenario, India have stringent regulatory requirements for approval of a new drug. The single regulatory approach for marketing authorization application (MAA) of a new drug product belonging to various categories of drugs (NCE, Biologicals, Controlled Drugs etc.) is utmost difficult. Therefore, the knowledge of precise and detailed regulatory requirements for MAA of different categories of drugs should be known to establish a suitable regulatory strategy. This article focuses on the drug approval process from regulatory authorities for different categories of pharma products. Finally, there needs to be a reaffirmation and fine balance between the tenacities of gaining market access of pharmaceuticals is to protect the public health and facilitate healthy growth of pharmaceutical manufacturers. Pharmaceutical product approval process should be seen as a critical step in ensuring access to safe and effective drugs.
Keywords: CDSCO, Clinical trials, DCGI, Marketing Authorization Application, Regulatory process.

I. INTRODUCTION

In India import, manufacturing, sale and distribution of drug is regulated under Drugs and Cosmetics Act 1940 and Drugs and Cosmetic Rules 1945 (hereinafter refer as Act) made there under. At present, bulk drug (Active Pharmaceutical Ingredients) and finished formulations are regulated under the said Act. Any substance falling within the definition of drug (Section 3b of the Act) required to be registered before import into the country. Not only drug but the manufacturing site needs to be registered for import. If the drugs, fall within the definition of New Drug (Rule 122 E of the Act), the new drug approval is the pre-requisite for submission of application for Registration and or import of drug. The application for Registration and import can be made to the Licensing Authority under the Act i.e. to the Drugs Controller General (I) at CDSCO, FDA Bhawan, Kotla Road, Near Bal Bhawan, New Delhi by the Local Authorized Agent of the foreign manufacturer having either manufacturing or sale License or by the foreign manufacturers' having a whole sale License in the country.
The proposed Guidance for applicants for submission of documents for Import of bulk drug(s) and finished formulation(s) are being uploaded for information of all the stakeholders likely to
be affected thereby for comments, if any.

All stakeholders are requested to send their comments and or suggestions on this document in writing for consideration of the CDSCO within a period of 20 days from the date of its uploading through post to the Drugs Control General (India), CDSCO, FDA Bhavan, Kotla Road, New Delhi – 110002 and through email at dci@nb.nic.in

The document is intended to provide non-binding guidance for use in the Import & Registration of bulk drug(s) and finished formulation(s) in India.

I.Purpose
To provide guidance for submission of application in Form 40 to CDSCO for Registration Certificate and issuing License for import of drugs into Indiawith CDCSO authority India, for issuance of import registration certificate for import of drugs into India.

II.Scope
This guidance is applicable to those drugs manufactured outside India, and the import registration to be issued(under Form 41) by the Central Drugs Standard Control Organization,(CDSCO) Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.

III.Responsibility

CDSCO: For implementing and to revise the same as notified, from time to time by the authority.

IV.Guidance:

1. An application shall be made to the Licencing Authority in Form 40, either bythemanufacturer himself, having a valid wholesale License, for sale or distribution of drugs or by his authorized agent in India either having a valid License to manufacture for sale of a drug or having a valid wholesale License for sale or distribution of drugs.

2. DETAILS TO BE CAPTURED IN FORM 40:

The authorized signatory name, designation, department, along with the complete address of the Company.

i) Authorized Signatory:

The person authorized preferably Director approved by the Board of Directors in case of company or by the proprietor in case of proprietorship firm. The application to accompany affidavit in respect of authorized person or the Power of Attorney in the name of the authorized person.

The Form shall detail the Foreign Manufacturer‘s contact person in the manufacturing site complete address, (i.e. address of the manufacturing premises), with corporate office address, along with the Telephone number, Fax number and E-mail address.

The Form shall detail the Foreign Manufacturer‘s contact person in the manufacturing site complete address, (i.e. address of the manufacturing premises), with corporate office address, along with the Telephone number, Fax number and E-mail address.

ii) The address of manufacturing premises shall be captured as below:

Undertaking on the document contents by the responsible person at the manufacturing site (contact person in the manufacturing site)

- In respect of import of more than one drug or class of drugs manufactured by the same manufacturer, provided that drug or the classes of drugs, are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit.
- In respect of the drugs manufactured in two or more factories situated in different places, for the manufacturing of the same or different drugs the name and address of both the manufacturing site should be included e.g. if the tablets are manufactured at one location and packed at another location, Name and Address of both the locations indicating the activity of each location

- The Form shall contain the complete and correct Name of the Drugs to be imported in India.

iii) The drug(s) name shall be captured as below:

- The brand name shall be captured.
- Different pack, pack size and/or different strengths of the same brand shall be captured.

Importer‘s undertaking letter declaring for the information specified in Schedule D (I) and Schedule D (II), provided by the original manufacturer.

The registration Fees amount (Challan number and date) shall be mentioned on Original TR 6 challan having complete name and address of the applicant and details of application to be enclosed.

iv) Fee structure for Import Registration under Form 40

- Fees and Form(s) and the undertakings as per Schedule D(I) (for registration of the manufacturing premises) and Schedule D(II) (for registration of the drugs):
- Applicant shall make a payment of 1500 USD (or its equivalent to Indian Currency), as registration fee for the Manufacturing premises.
- Applicant shall make an payment of 1000 USD (or its equivalent to Indian Currency), as registration fee for a single drug and additional fee of 1000 USD for each additional drug in case the manufacturing site remains the same. Fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110 001 or any other Bank, as notified, from time to time by the authority.

v) Challan and Bank details:

Fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110 001 or any other Bank, as notified, from time to time by the authority.

The pay order cheque to be in favour of Pay & Accounts Officer, DGHS, Nirman Bhavan, New Delhi-01 Challan

means-the receipt of the Cash paid into the bank, which is attested by the bank with seal and date.
The fee to be credited under the following details
Electronic Payment: In case of any direct payment of fees by manufacturer in the country of origin through ECS (Electronic Clearance System) from any bank in the country of origin to Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110 001, through the Electronic Code of the Bank in the Head of Account, ―104 – Fees andFines‖ and Original receipt of the said transfer can be considered as an equivalent to bank Challan, subjected to approval by Bank of Baroda.

Applicant is liable to pay 5000 USD (or its equivalent to Indian Currency) for Expenditure [Inspection fees + expenditure on inspection to be borned by company] as may be required for
Inspection or Visit of manufacturing premises.
The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the central government in India or abroad, as required for examination testing and analysis of drugs.

- Applicant has to pay a fee of 300 USD (or its equivalent to Indian Currency) for a duplicate copy of the registration certificate, if the original is defaced, damaged or lost.

Registration time provided further that if the application is complete in all respects and information specified in D (I) & D (II) are in order, the licencing authority shall within 9 months from the date of receipt of application issue such Registration Certificate, and in exceptional circumstances and for the reasons to be recorded in writing, the Registration Certificate may be issued within such extended period not exceeding 3 months as the licencing authority may deemed fit.

- Undertaking for the compliance of the terms and conditions required, by the applicant to obtain the registration certificate and to keep the validity of the registration certificate.
- The data specified in Schedule D (I) and Schedule D (II) shall be enclosed along with the covering letter and Table of content.

VI. Details to be captured in the Covering Letter:

- Information of the drugs to be imported
- Manufacturer information like address and contact details.
- Brief information about the application and List of Documents-

- Original Challan and the details of the Challan
- Form 40
- Schedule D(I) documents as provided by the drug(s) manufacturer (Module 1 of CTD format)
- Schedule D(II)-documents as provided by the drug(s) manufacturer(Module 2 to 5 of CTD format)
- Power of Attorney issued by the manufacturer
- Copy of Whole Sale License of applicant
- Copy of Authorization letter of Applicant
- An Undertaking shall be submitted by the proprietor of the firm in case of proprietorship firm and in case of Private limited Company, by the board of Directors.

2. Requirements for Common Submission Format for Registration of bulk drug(s) and finished formulation(s) in India

The following documents are required to be submitted in the following manner and order for the Import & Registration of the bulk drug(s) and finished product(s) in India: -
Applicants are requested to submit application in 3 or more different
files as follows: -

1. Covering Letter– The covering letter is an important part of the application and should clearly specify the intent of the application (whether the application for the registration of the manufacturing site is being submitted for the first time, whether the application is for reregistration/ renewal or is for the endorsement of additional products to an existing Registration Certificate) the list of documents that are being submitted (Index with page no‘s) as well as any other important and relevant information may be provided in the covering letter. The covering letter should be duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory along with the name and address of the firm. Any exemption to the submission requirement be clearly specified in the covering letter on the firm/company letter head and justified in the submissions.
A Resolution shall be submitted by the proprietor of the firm in case of proprietorship firm and by the board of

Directors in case of Private limited Company/ firm.
2. **An Authorization letter** in original issued by the Director/Company Secretary/Partner of the Indian Agent firm revealing the name & designation of the person authorized to sign (along with the name and address of the firm) legal documents such as Form 40, Power of Attorney etc. on behalf of the firm should be submitted at the time of submission of the application for registration (Rule122A). It shouldhave validity period as per company's policies. Duly self-attested photocopies of the Authorization letter may be submitted at the time of submission of subsequent applications.
3. A duly filled **Form 40** as per the proforma prescribed in the Drugs & Cosmetics Rules, signed & stamped by the (Local Authorized Agent/manufacturer) along with name & designation and date. Form - 40 should be signed by the (Local Authorized Agent or manufacturer and should have valid sale or manufacturing License in India. Form 40 proforma is enclosed at Annexure –I.
4**. TR 6 Challan**: In case of any direct payment of fee by the manufacturer in the country of origin, the fee shall be paid through Electronic Clearance System (ECS) from any bank in the Country of Origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the electronic code of the bank in the head of Account stated above and the original receipt of the said transfer shall be treated as an equivalent to the Bank Challan, subject to the approval by the Bank of Baroda that they have received the payment.
5. **Power of Attorney** - The authorization by a manufacturer to his agent in India shall be documented by a Power of Attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, The certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate. Apostille Power of Attorney from Hague convention member countries is also acceptable. Performa for Power of Attorney is enclosed at Annexure III. The authorized agent will be responsible for manufacturer's business activity, in India.
While submitting the Power of Attorney, the following points should be kept in mind: -
It should be co-jointly signed and stamped by the manufacturer as well as the Indian Agent indicating the name & designation of the authorized signatories (along with the name and address of the firm).
It should clearly list the names of all the proposed drugs if possible along with their specific Indication and/or intended use. Further, the names of the proposed drug should correlate with those mentioned in the Form 40, Free Sale Certificate or Certificate of pharmaceutical product (COPP) as per WHO-GMP certification scheme.
The names & addresses of the manufacturer (Contract manufacturer name from different sources) as well as the Indian Agent stated in the Power of Attorney should correlate with the Form 40. Multiple sites are in tabular form.
It should be valid for the period of said Registration Certificate. It implies that a fresh POA is to be submitted at the time of revalidation of RCa.

II. DISCUSSION

I.Rules Related to Import and Registration of bulk drug(s) and finished formulation(s) in India

24. Form and Manner of Application for Import License

(1) An application for an import License shall be made to the licensing authority in Form 8 for drugs excluding those specified in Schedule X, and in Form 8-A for drugs specified in Schedule X, either by the manufacturer himself having a valid wholesale License for sale or distribution of drugs under these Rules, or by the manufacturer's agent in India either having a valid License under the Rules to manufacture for sale of a drug or having a valid wholesale License for sale or distribution of drugs under these Rules, and shall be accompanied by a License fee of one thousand rupees for a single drug and an additional fee at the rate of one hundred rupees for each additional drug and by an undertaking in Form 9 duly signed by or on behalf of the manufacturer:
Provided that in the case of any subsequent application made by the same importer for import License for drugs manufactured by the same manufacturer, the fee to accompany each such application shall be one hundred rupees for each drug:
(2) Any application for import License in Form 8 or Form 8-A, as the case may be, shall be accompanied by a copy of Registration Certificate issued in Form 41 under Rule 27-A:
Provided that in case of emergencies the licensing authority may, with the approval of the Central Government, issue an import License in Form 10 or 10-A, as the case may be, without the issuance of Registration Certificate under Rule 27-A, for reasons to be recorded in writing.
Provided further that Registration certificate shall not be required to be accompanied with an application for an import License under the Rules for the import of in-vitro diagnostic kits and regents, except for the diagnostic kits notified from time to time under sub-clause (iv) of clause (b) of section 3.]

(3) A fee of two hundred and fifty rupees shall be paid for a duplicate copy of the License issued under this Rule, if the original is defaced, damaged or lost.

24-A. Form and Manner of Application for Registration Certificate.—

(1) An application for issue of a Registration Certificate shall be made to the licensing authority in Form 40, either by the manufacturer himself, having a valid wholesale License for sale or distribution of drugs under these rules, or by his authorised agent in India, either having a valid License under the rules to manufacture for sale of a drug or having a valid whole ale License for sale or distribution of drugs under these rules, and shall be companied by the fee specified in sub-rule (3) and the information‘s and undertakings specified in Schedules D-I and D-II duly signed by or on behalf of the manufacturer.

(2) The authorisation by a manufacturer to his agent in India shall be documented by a power of attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate.

(3)(i) A fee of one thousand and five hundred US dollars [or s equivalent in Indian rupees] shall be paid along with the application in Form 40 as registration fee for his premises meant for manufacturing of drugs for import into and use in India.

(ii) A fee of one thousand US dollars [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 for the registration of a single drug meant for import into and use in India and an addition fee at the rate of one thousand US dollars for each additional drug:

Provided that in the case of any subsequent application for registration of additional drugs by the same manufacturer, the fee to company shall be one thousand US dollars [or its equivalent in Indian rupees] for each drug.

(4) The fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to t e, by the Central Government, to be credited under the Head of Account ―0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines‖: Provided that in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through lectronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account ―0210 Medical and Public Health, 04- Public Health, 104-Fee and Fines‖, and the original receipt of the said transfer shall be treated as an equivalent to the bank challan, subject to the approval to the Bank of Baroda that they have received the payment.

(5) The applicant shall be liable for the payment of a fee of five thousand US dollars [or its equivalent in Indian rupees] for expenditure as may be required for inspection or visit of the manufacturing premises or drugs, by the licensing authority or by any other persons to whom powers have en delegated in this behalf by the licensing authority under Rule 22.

(6) The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the Central Government India or abroad, as may be required for examination, tests and analysis of drug.

(7) A fee of three hundred US dollars [or its equivalent i Indian rupees] shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

(8) No Registration Certificate shall be required under these Rules in respect of an inactive bulk substance to be used for a drug formulation, with or without pharmacopoeial conformity

25B Registration Certificate for Import of Drugs Manufactured by One

Manufacturer:—

(1) A single application may be made, and a single Registration Drugs and Cosmetics Rules, 1945 Certificate in Form 41 may be issued in respect of the import of more than one drug or class of drugs, manufactured by the same manufacturer:

Provided that the drug or classes of drugs, are manufactured at one factory or more than one factory functioning conjointly as a sing manufacturing unit: Provided further that if a single manufacturer has two r more factories situated in different places manufacturing the same or different drugs, separate Registration Certificates shall be required in respect of the drugs manufactured by each such factory.

27-A Grant of Registration Certificate-

(1) On receipt of an application for Registration Certificate in the Form and manner specified in Rule 24-A, the

licensing authority shall, on being satisfied, that, if granted, the conditions of the Registration Certificate will be observed, issue a Registration Certificate in Form 41:
Provided further that if the application is complete in all respects and informations specified in Schedules D-I and D-II are in order, the licensing authority shall, within nine months from the date of receipt of an application, issue such Registration Certificate, and in exceptiona circumstances and for reasons to be recorded in writing, the Registration Certificate may be issued within such extended period, not exceeding three month as the licensing authority may deem fit.
(2) If the applicant does not receive the Registration Certificate within the period as specified in the proviso to sub-rule (1), he may appeal to the Central Government and the Central Government may after such enquiry into the matter, as it considers necessary, may pass such orders in relation thereto as it thinks fit.]

28-A Duration of Registration Certificate.—-

A Registration Certificate, unless, it is sooner suspended or cancelled, shall be for a period of three years from the date of its issue:
Provided that if the application for a fresh Registration Certificate is made nine months before the expiry of the existing certificate, the current Registration Certificate shall be deemed to continue in force until orders are passed on the application.

29-A Suspension and cancellation of Registration Certificate. —

If the manufacturer fails to comply with any of the conditions of the Registration Certificate, the licensing authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the Registration Certificate for such period as it thinks fit either wholly or in respect of some o the substances to which it relates:
Provided that a person, who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government, and the Central Government ay, after such enquiry into the matter as it considers necessary and after give the appellant an opportunity for representing his views in the matter, pass such orders in relation thereto as it thinks fit.

II. Importing Medicines Into India

- Importing medicines or drugs which nothing but bringing branded name medicines from outside country to marketing in India through legal registration.
- The various provisions of the Drugs & Cosmetics Rules, thereby introducing a new provision for the registration of the manufacturing premises of foreign drug manufacturer and the individual drugs prior to their import into the country.
- Under the new dispensation, foreign manufacturers have to apply for registration certificate for their manufacturing premises and the individual drugs to be imported.
- The applications can be made by authorized agents of foreign firms in India.
- The process of receiving import registration can take up to 12 months. Once you have import registration for a drug, you can apply for a simple import license via Form 8 or Form 8A, which is needed for customs clearance.
- The validity of registration certificates will be 3 years from the date on which these are issued.
- PITC Pharma is a subsidiary of the PITC & an affiliate of the National Development Company - PITC-supplies medicines to government hospitals, health centers, prisons, and community pharmacies.
- According to the Indian pharmaceutical group, medicines produced from their country cost about 15-16 times cheaper than the medicines sold in the Philippines.
- Medicines have become the latest among Indianimports.
- When compared to previous year, India imported active Pharma ingredients and drug intermediates worth $4.6 billion (Rs.25,000 crore).
- Mostly the Pharma sector imports raw materials like chemicals intermediates and active pharmaceuticals ingredients (APIs).
- Import of Drugs is regulated as per the Foreign Trade Policy of Government of India.
- Sometimes, India has exported more pharmaceutical products than it imports.
- The pricing methods for imported bulk drugs were based on the landed cost (inclusive of import & customs duty), which was the maximum permissible selling price.
- All drugs to be imported require their own import registration.

- Demand in India is growing rapidly, due to rising population, increasing elderly people, though importing medicines is considered set to rise strongly.

Technology

- Indian pharmaceutical environment.
- Global Pharmaceutical Trade and Contribution of India.
- Medical technology industry in India
- Import of drugs for marketing in India.
- Pharmaceutical Producers of India.
- Pharmaceuticals Distribution in India.
- To make India the Global Provider of Medicines at Reasonable Prices.

Forms

- Application Form for issue of import certificate for import of drugs.
- Application form for allotment of quota of drug.
- Application of issue of registration certification for import of drugs into India.
- Form of undertaking to accompany an application for an import license.

Registration

- Drug Registration and Import.
- Registration and Document Requirements for Import.
- Registration certificate issued for import of cosmetics into India under drugs & Cosmetic Rules.
- Import and Registration for marketing of drugs in India.

Rules & Regulation

- Regulatory approaches & criteria for approvals of biotech medicines in India.
- Regulatory system and present scenario of Indian Pharmaceutical industry.
- Biologics Regulation in India.
- Drug Regulations in India.
- Regulatory issues in the Indian Pharmaceutical Industry.
- Indian Regulations & Guidelines.

Guidance

- Guidance document on common submission format for import License.
- Guidelines for import & export of drugs & cosmetics.
- Guide to Export & Import.
- Draft Guidance on approval of new drugs.
- Regulatory requirements for marketing authorityin India.
- Import/Export Restrictions & Prohibitions.
- Drug and Cosmetics Act & Rules.

Trends

- Trends in India's Trade in Pharmaceutical Sector.
- Prescription Drug Importation.
- Parallel Imports in Pharmaceuticals.
- Re-importation in Pharmaceuticals.
- Trends in Trade Balance of pharmaceutical products.

Import Status

- Importation of Active Pharmaceutical Ingredient Requirements.
- Global Pharma looks to India.
- Indian Pharmaceutical Sector - Current Status
- India's Pharmaceutical industry on course of globalization.

- Opportunities for the Indian Pharma industry.
- Exhausting patent rights in India: Parallel Imports.
- Medicine Import data & import statistics in India.

Study

- Drug Trafficking In India.
- China & India as suppliers of affordable medicines to developing countries.
- Product patents & Access to medicines in India.
- Monopolies pharmaceutical industry in India.
- Importing Indian Generic Drugs Following TRIPS.

III.Guidelines on import procedures for pharmaceutical products

Public health considerations demand that pharmaceutical products should not be treated in the same way as ordinary commodities. Their manufacture and subsequent handling within the distribution chain, both nationally and internationally, must conform to prescribed standards and be rigorously controlled. These precautions serve to assure the quality of authentic products, and to prevent the infiltration of illicit products into the supply system.

Within the context of its revised drug strategy. adopted in 1986 by the Thirty-ninth World Health Assembly in resolution WHA39.27, WHO developed "Guiding principles for small national drug regulatory authorities" (1, 2) which established a regulatory approach in line with the resources available within a small national regulatory authority, and were intended to assure not only the quality. but also the safety and efficacy, of pharmaceutical products distributed under its aegis.

The principles emphasize the need for the effective use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. This constitutes a formal agreement between participating Member States to provide information on any product under consideration for export, notably on its registration status in the country of origin and whether or not the manufacturer complies with WHO's guidelines on good manufacturing practices (GMP) for pharmaceutical products (3).

To be fully effective, the Scheme needs to be complemented by administrative and other safeguards aimed at ensuring that consignments of imported products are in conformity in all particulars with the relevant import licence and that they remain secure within the distribution chain. Storage and transit tacilities must be proof against tampering and adverse climatic conditions, and relevant controls must be applied at every stage of transportation.

Pharmaceutical products containing substances controlled under the international conventions ha e long been subjected to rigorous border controls. Some of these controls, and particularly those designed to prevent the diversion and illicit interchange of products during transit, are relevant to all pharmaceutical products. and are therefore included in these guidelines. Full details of the special import controls required for narcotic drup•s and psychotropic substances are p•iven in the Appendix.

Objectives and scope

The following guidelines, which stem from the above considerations, have been developed in consultation with national drug regulatory authorities, the pharmaceutical industry, the World Customs Organi- zation, and the United Nations International Drug Control Programme.

The guidelines are directed to all parties involved in the importation of pharmaceutical products, including national drug regulatory authorities, competent trade ministries, customs authorities, port authorities, and importing agents.

They are intended to promote efficiency in applying relevant regulations, to simplify the checking and handling of consignments of pharmaceutical products in international transit and, inter alia, to provide a basis for collaboration between the various interested parties.

They are applicable to any pharmaceutical product destined for use within the country of import, and are intended to be adapted to prevailing national conditions and legal requirements.

Legal responsibilities

The importation of pharmaceutical products should be effected in conformity with regulations promulgated under the national drugs act or other relevant legislation and enforced by the national drug regulatory authority. National guidelines providing recommendations on the implementation of these

regulations should be drawn up by the national drug regulatory authority in collaboration with the customs authority and other interested agencies and organizations.

All transactions relating to the importation of consignments of pharmaceutical products should be conducted either through the governmental drug procurement agency or through independent wholesale dealers specifically designated and licensed by the national drug regulatory authority for this purpose

The importation of all consignments of pharmaceutical products should be channelled exclusively through customs posts specifically designated for this purpose.

All formalities undertalcen on importation should be coordinated by the customs service, which should have the authority to request the services of an official pharmaceutical inspector as occasion demands. When justified by the workload, a pharmaceutical inspector may be stationed full time at one or more of the designated ports of entry.

The customs authority should have the discretionary powers to request technical advice and opinions from other appropriately qualified persons, should this be warranted by particular circumstances.

IV.Regulatory Issues in the Indian Pharmaceutical Industry

This section undertakes a review and assessment of regulatory issues in the Indian pharmaceutical industry. Understanding the regulatory scenario in this sector is extremely crucial not only due to the rapid and ongoing changes at the global level, largely with reference to good manufacturing practices (GMP), good clinical practices (GCP) and good laboratory practices (GLP) but also due to the onus on the regulatory bodies to ensure a healthy supply of quality drugs at affordable prices to the Indian masses.

The present section begins with a brief description of the major regulatory bodies monitoring the Indian pharmaceutical sector. It then undertakes a review of the prevailing mechanisms for drug regulation and temporal progression of some predominant policy measures and Acts. The section subsequently provides a comprehensive account of the status and key guidelines pertaining to the dimensions of drug pricing, patent related issues, GMP and clinical trials, in addition to a brief review of standards for medical devices and biotech products. It concludes with an assessment of the deficiencies of present regulatory regime and some new initiatives by the State to ensure the production and marketing of safe and efficacious drugs at affordable prices in the domestic sphere and to sustain current growth prospects in the global markets.

Major bodies regulating drugs and pharmaceuticals

The principal regulatory bodies entrusted with the responsibility of ensuring the approval, production and marketing of quality drugs in India at reasonable prices are:

The Central Drug Standards and Control Organization (CDSCO), located under the aegis of the Ministry of Health and Family Welfare. The CDSCO prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country; regulates the market authorization of new drugs and clinical trials standards; supervises drug imports and approves licences to manufacture the above-mentioned products;

The National Pharmaceutical Pricing Authority (NPPA), which was instituted in 1997 under the Department of Chemicals and Petrochemicals, which fixes or revises the prices of decontrolled bulk drugs and formulations at judicious intervals; periodically updates the list under price control through inclusion and exclusion of drugs in accordance with established guidelines; maintains data on production, exports and imports and market share of pharmaceutical firms; and enforces and monitors the availability of medicines in addition to imparting inputs to Parliament in issues pertaining to drug pricing.

The Department of Chemicals and Petrochemicals also oversees policy, planning, development and regulatory activities pertaining to the chemicals, petrochemicals and pharmaceutical sector. The responsibilities assumed by this body are relatively broader and varied in comparison to the other two bodies. The main aspects of pharmaceutical regulation are thus divided between the above two ministries. The Ministry of Health and Family Welfare examines pharmaceutical issues within the larger context of public health while the focus of the Ministry of Chemicals and Fertilizers is on industrial policy. However, other ministries also play a role in the regulation process. These include the Ministry of Environment and Forests, Ministry of Finance, Ministry of Commerce and Industry and the Ministry of Science and Technology. The process for drug approval entails the coordination of different departments, in addition to the DCGI, depending on whether the application in question is for a biological drug or one based on recombinant DNA technology. Issues related to industrial policy such as the regulation of patents, drug exports and government support to the industry are governed by the Department of Industrial Policy and Promotion and Directorate General of Foreign Trade, both under the aegis of Ministry of

Commerce and Industry and the Ministry of Chemicals and Fertilizers. With respect to licencing and quality control issues, market authorization is regulated by the Central Drug Controller, Ministry of Health and Family Welfare, Department of Biotechnology, Ministry of Science and Technology (DST) and Department of Environment, Ministry of Environment and Forests. State drug controllers have the authority to issue licences for the manufacture of approved drugs and monitor quality control, along with the Central Drug Standards Control Organization (CDSCO).

Prevailing Mechanisms

This sub-section primarily focuses on major regulatory policies and mechanisms in relation to drug pricing and development of standards for ensuring safety and efficacy.

In India, drug manufacturing, quality and marketing is regulated in accordance with the Drugs and Cosmetics Act of 1940 and Rules 1945. This act has witnessed several amendments over the last few decades. The Drugs Controller General of India (DCGI), who heads the Central Drugs Standards Control Organization (CDSCO), assumes responsibility for the amendments to the Acts and Rules. Other major related Acts and Rules include the Pharmacy Act of 1948, The Drugs and Magic Remedies Act of 1954 and Drug Prices Control Order (DPCO) 1995 and various other policies instituted by the Department of Chemicals and Petrochemicals.

Some of the important schedules of the Drugs and Cosmetic Actsi include: Schedule D: dealing with exemption in drug imports, Schedule M: which, deals with Good Manufacturing Practices involving premises and plants and Schedule Y: which, specifies guidelines for clinical trials, import and manufacture of new drugs

In accordance with the Act of 1940, there exists a system of dual regulatory control or control at both Central and State government levels. The central regulatory authority undertakes approval of new drugs, clinical trials, standards setting, control over imported drugs and coordination of state bodies' activities. State authorities assume responsibility for issuing licenses and monitoring manufacture, distribution and sale of drugs and other related products.

CONCLUSION

Any medicinal agent to be marketed in the United Kingdom has to follow the guidelines and regulations framed by MHRA, a regulatory authority which approves the drug products. The objective of this review article is to highlight information regarding the requirements, the different types of submissions for the registration of a medicinal product in a market in the UK. It also includes all the details about the fee for the application and the time period for the approval of the application after the submission of the application. By knowing the requirements of the MHRA guidelines and regulations, it is easy for a product to get into the UK market.

The Indian Pharmaceutical Industry has shown great potential and continues to grow consistently. The Indian generic drug sector is robust and is establishing its presence in foreign markets too. The new- drug sector is also expected to record a healthy growth owing to significant industrywise increase in R&D expenditure and proposed new drug launches. However, since health is an important subject, the industry continues to be heavily regulated. Multiple Ministries continue to regulate the pharmaceutical industry such as the Health Ministry, Chemicals and Fertilizers Ministry, Science and Technology Ministry, Food Ministry etc. Numerous legislations, regulations and judgments affecting the industry have come into existence recently and numerous others have been proposed. The Industry will have to realign itself with these legal changes in order to ensure continuance of its success story.

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