Regulatory Issues And Recent Changes In Drug Laws

written by Sanjay Kumar | February 23, 2021

This article undertakes a review and assessment of regulatory issues in the Indian pharmaceutical industry. Understanding the regulatory process in this sector is extremely crucial due to the rapid and ongoing recent Changes In Drug Laws at the global level as well as at Indian drug regulatory landscape. The Drugs and Cosmetics Act of 1940 and Rules 1945 have witnessed several amendments over the last few decades. In the year 2020, the Drugs and Cosmetics Rules was amended on a number of occasions and the key amendments are :

Retail sale of drugs to the doorstep of consumers is essential to meet the requirements of emergency arising due to pandemic COVID-19[1]

The Central Government has permitted the retail sale of drugs to the doorsteps of the consumer by any person holding a license in Form-20 or Form-21 under the Drugs and Cosmetics Rules, 1945 to sell, stock or exhibit or offer for sale, or distribute drugs by retail, intends to sell any drug including the drugs specified in Schedule H except,

1. narcotics, psychotropics and controlled substances as defined in the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), and
2. the drugs as specified in Schedule H1 & Schedule X

The licensee can sell such drugs provided that any such sale specified in Schedule H shall be based on receipt of prescription physically or through e-mail and such sale of drugs shall further be subject to the following conditions:

1. The licensee shall submit an e-mail ID for registration with the licensing authority if prescriptions are to be received through email.
2. The drugs shall be supplied at the doorstep of the patients located within the same revenue district where the licensee is located.
3. In case of chronic diseases, the prescription shall be dispensed only if it is presented to the licensee within 30 days of its issue and in acute cases, the prescription shall be dispensed only if it is presented to the licensee within 7 days of its issue.
4. The bill or cash memo shall be sent by the return email and records of all such transactions shall be maintained by the licensee.

Exemption of Sale License for Sanitizers

The Central Government has notified[2] that the drug, namely, hand sanitizer shall be exempted from the requirement of sale licence for its stocking or

sale under the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, subject to the condition that provisions of condition (17) of rule 65 of the said Rules are complied with by the person stocking or selling hand sanitizers.

Rule 65 (17) of the Drugs and Cosmetics Rules, 1945 states that no drug shall be sold or stocked by the licensee after the date of expiration of potency recorded on its container, label or wrapper, or in violation of any statement or direction recorded on such container, label or wrapper.

The term “marketer” is defined to fix the responsibility of the marketer for quality and regulatory compliance

The Central Government has amended Rule 2 of the Drugs and Cosmetics Rules, 1945, to include term marketer under clause (ea).

The term “Marketer” means a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer under an agreement for the marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution.

Further, Rule 84D has been inserted which provides for an agreement for marketing. This rule makes it mandatory for every marketing company to enter into an agreement for the marketing of the drug.

Rule 84 E has been inserted to define the responsibility of the marketer. This equates the responsibility of marketer with a manufacturer for the quality of drugs and regulatory compliance.

Further, a sub-clause clause (xiii) in clause (1) Rule 96 has been inserted regarding the labelling requirement of drugs by marketer providing that :

1. the name of the marketer of the drug and its address, in case the drug is marketed by a marketer must be there.
2. if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the marketer is shown.

This amendment comes into force wef 1st March 2021. However, the amendment does not provide any detailed procedure or guidelines on how a marketing company will maintain the quality of the drugs. So far, the marketing companies are marketing the drugs under contract manufacturing agreement whereby quality of drugs and regulatory compliances are the responsibility of manufacturers.

The marketing companies are selling/distributing the drugs under wholesale license with storage conditions. In Not of Standard Quality cases, marketing companies were made co-accused for the failure of quality of drug and the plea under section 19 of the Drugs and Cosmetics Act, 1940 was available to the marketer if the drugs are obtained from a licensed manufacturer.

Now, In the light of a new amendment, a marketing company has to develop a mechanism to ensure the quality of drugs manufactured by a manufacturer and also comply with all regulatory compliances applicable to drugs.[3]

Regulate activities of blood centres by providing educational qualification of personnel, criteria for blood donation, and the requirement for organizing blood donation camps.[4]

The Central Government has amended certain provisions of part XB, Rule 122EA, 122G. Some of the key Recent Changes In Drug Laws are:

1. The words ‘Blood Bank’ shall be substituted by the words ‘Blood Centre’.
2. The operation of Blood Centre or processing or both of whole human blood for components shall be conducted under the active direction and personal supervision of competent technical staff consisting of at least one person

who is whole time employee and who is Medical Officer, and possessing an MBBS.

3. Blood Centre organizing blood donation camps shall have whole time or part time counselling staff (Counsellor or Medical Social Worker) possessing, for eg. Master's degree in social work, sociology, psychology with six months of experience.
4. Some of the criteria to donate blood are:
5. The donor shall be in good health, mentally alert and physically fit and shall not be an inmate of jail or any other confinement.
6. Minimum age-18 years; Maximum age-65 years. First time donor shall not be over 60 years of age. For a regular donor, upper limit is 65 years.
7. Blood collection: 350 ml- 45 kg 450ml– more than 55 kg
8. Donation interval: For whole blood donation, once in three months (90 days) for males and four months (120 days) for females.

Medical Device declared as "Drug"

The Central Government specifies the following devices intended for use in human beings or animals as drugs. All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals but which may assist in its intended function by such means for one or more of the specific purposes of –

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; (iii) investigation, replacement or modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) disinfection of medical devices; and (vi) control of conception.

The Central Government has declared medical devices as drugs[5]. These devices are covered by the definition of medical devices under Rule 3(zb) of Medical Devices Rules, 2017. The Central Government has notified devices to cover practically all devices intended to be used for diagnosis, mitigation, treatment, prevention of disease or disorder.

Further, the Central Government inserted Chapter IIIA to provide for the regulation of registration of these devices. The Medical devices referred to in sub-rule (1)of Rule 19 A shall be registered with the Central Licensing Authority through an identified online portal established by the Central Drugs Standard Control Organisation for this purpose. The registration under this Chapter shall be on a voluntary basis for a period of eighteen months from the commencement of this Chapter thereafter it shall be mandatory.[6]

Some of the examples of medical devices mentioned in Anexure of Rule 19 A are:

- Condoms
- Tubal Rings
- Nebulizer (effective from 1 Jan.2021)
- Blood Pressure Monitoring Device (effective from 1 Jan.2021)
- Glucometer (effective from 1 Jan.2021)
- Digital Thermometer (effective from 1 Jan.2021)

- [1] G.S.R. 220(E) dated 26th March, 2020 MINISTRY OF HEALTH AND FAMILY WELFARE
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- [2] S.O. 2451(E) dated 27th July 2020 MINISTRY OF HEALTH AND FAMILY WELFARE
- [3] GSR 101(E) dated 11.02.2020 Ministry of Health & Family welfare
- [4] GSR 166(E) dated 11.03.2020 Ministry of Health & Family welfare
- [5] SO 648(E) dated 11.02.2020 w.e.f. 01.04.2020 Ministry of Health & Family Welfare
- [6] GSR 102(E) dated 11.02.2020 also effective from 01.04.2020

Contributed By- Sanjay Kumar, Partner - Pharma & Life Sciences
King Stubb & Kasiva,
Advocates & Attorneys
Click Here to Get in Touch
New Delhi | Mumbai | Bangalore | Chennai | Hyderabad | Kochi
Tel: +91 11 41032969 | Email: info@ksandk.com