Minutes of meeting of CDSCO with stakeholders for obtaining Import License without Registration Certificate for Radiopharmaceuticals held on 12.04.19 at Conference Hall, CDSCO (HQ), New Delhi.

List of Participants:

1. **Dr. S. Eswara Reddy,** Drugs Controller General (India), Central Drugs Standard Control Organization, New Delhi
2. **Shri Jayant Kumar,** Deputy Drugs Controller (India), Central Drugs Standard Control Organization, New Delhi.
3. **Shri Gaurav Kumar,** Assistant Drugs Controller (India), Central Drugs Standard Control Organization, New Delhi.

Representative from Stakeholder:

1. **Dr. Jasmeet Sahni,** Medical Director, Wipro GE Healthcare.
2. **Shri Vibhav Garge, Vice President,** Wipro GE Healthcare.
3. **Shri K. L. Narasimhan, Regulatory Affaire & Head,** Wipro GE Healthcare.
4. **Shri Taranjit Singh,** B. J. Madan & Co.
5. **Shri Pankaj,** Syphen Technologies Ltd.
6. **Shri Ankush Shah,** Syphen Technologies Ltd**.**
7. **Shri Anil Rajput,** Vishat Diagnostics Ltd.
8. **Shri Ashish Kumar,** Vishat Diagnostics Ltd**.**
9. **Ms. Stuti A. Saxena,** Sansoxs Biotech(P) Ltd.
10. **Shri Jagat Singh,** Sansoxs Biotech(P) Ltd.
11. **Shri Devendra Singh,** Noki Technologies Pvt. Ltd.
12. **Shri Adarsh Kumar,** Shreeji Imagine & Diagnostic Ltd.

The details discussion made during the meeting are as under:

- Dr. S. Eswara Reddy, DCG(I) welcomed all the stakeholders and officials of CDSCO. He briefed the purpose of meeting and the requirement of Import & Registration Certificate for Radiopharmaceuticals under provisions of the Drugs and Cosmetics Act and Rules made thereunder.
- DCG(I) explained the current practices followed for grant of Import & Registration Certificate and added that various office memorandum were issued for Import regulation of Radiopharmaceuticals. Earlier Import Licenses had been issued under Rule 24 (2) *"Provided that in case of*

emergencies the licensing authority may, with the approval of the Central Government, issue an import licence 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" for Import of Radiopharmaceutical as an emergency. It was further stated that this is a provision for being used only during the emergency. It should not be construed as a general practice.

- Stakeholders informed that they had already got waiver for the requirement of Registration Certificate and were importing these Radiopharmaceutical products under Import License for which there are no indigenous manufacturer available.
- The representative of stakeholders also stated that there is high demand/requirement of these Radio pharmaceuticals whereas the production capacity of indigenous manufacturers is inadequate to fulfil these demand. During the discussion, it was clarified to the stakeholders that the high demand and large business volume cannot be considered as an emergency.

After detailed deliberation, following decisions were taken:

1. All representatives of the stakeholder agreed to apply for the grant of Registration Certificate for the product for which they had applied for the Import License within or maximum period of six months under the provision of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.
2. For those stakeholders who had submitted application for Import Licence without Registration Certificate, the Import Licence will be granted with the approval of Central Government, subject to condition that the Registration Certificate shall be obtained within or maximum period of six months under the provision of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.
3. CDSCO will examine all such application made for obtaining the Registration Certificate for Radiopharmaceuticals on priority.
4. The applicants are also required to submit the application for New Drug permission under the Drugs and Cosmetics Act, 1940 and Rules made thereunder. The safety and efficacy of these products will be evaluated on the basis of data presented by the applicants before Subject Expert Committee (SEC) on Radiopharmaceuticals.

The meeting ended with the vote of thanks

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