**Date:** (Monday) 21st August-2023

**Time:**3:00 pm to 4:00 pm

**Type of Workshop:** Zoom (virtual mode)

**Number of participants**: 36

**Presenter**: Dr. MR Rajagopal, Chairman Emeritus-Pallium India and the Director of WHO Collaborating Centre-Trivandrum Institute of Palliative Sciences, Trivandrum, Kerala

**Participants:**

1. Shri DK Tiwari, Assistant Commissioner Drugs, FDA, Lucknow, UP
2. Dr Alka Sharma, State NCD cell, DGMH Lucknow, UP
3. Dr Sanjay Dhiraj, Medical Superintendent, SGPGIMS Lucknow, UP
4. More than 30 doctors and paramedical staff from government and private hospitals UP

**Highlights of the discussion:**

* It was clarified that government institutes are deemed RMIs. If they have a doctor trained in pain management or palliative care, they do not have to apply for RMI certificate; but they do have to submit their annual estimates on Form 3J and maintain records like any other RMI. Please refer to the attached office order issued by Additional Secretary, Shri B. N Sharma in the year 2016.
* In response to Dr. Nimisha’s (BHU Varanasi) question on having a separate pharmacist to maintain and dispense opioid stock, Dr. Rajagopal shared that as per the decision of the Drug Controller General of India dated 4/01/2001 (attached) palliative care centres are exempted from the need for a pharmacist for stocking and dispensing oral morphine. However, in bigger hospitals, it is convenient for a pharmacist to be responsible for all documentation stock keeping and dispensing. Please refer to the attached document, in the first column the title is on exemption. The exemption is from 'The provisions in chapter IV of the ACT and rules made thereunder which require them to be covered by sale license'. Sale license is the one that stipulates the need for a pharmacist. The next sentence brings out palliative care centres as the condition for exemption.
* SDC, Shri DK Tiwari, assured everyone that their office will provide all support to the institutes who apply for morphine. They can reach out to him directly at 9935524199. He and his team would like to support this noble work of pain relief to suffering patients in all ways possible.
* In response to another question, Dr. Rajagopal clarified that once approved as an RMI, the institution can place order with the supplier as many times as necessary. However, if the quantity exceeds the submitted annual estimate, it is necessary to send a revised estimate to SDC office in the Form 3 J. After that, the RMI can place a direct order with the vendor. In the new rules of 2015, quota approval from SDC has been removed. Please refer to Rule no. 52T in the attached gazetted document by Department of Revenue of Government of India. However, often the vendor is likely to crosscheck with the SDC to ensure that everything is in order.
* Responding to Dr Alka Sharma, DHS official for palliative care, Dr. Rajagopal mentioned that a government institution does not need prior approval as RMI because according to the new rules of 2015, all government institutes are deemed RMIs. But the institution still needs to send the annual estimate to inform SDC about the institution where opioids are being stocked and dispensed. Please refer to the gazetted order attached with this email - rules of the NDPS Amended Act 2015 by Ministry of Revenue.
* Both the SDC and Dr. Alka agreed that for UP government institutions, the procurement can be done through the central body – UP Medical Supply Corporation.
* The following is the checklist needed to apply for an RMI certificate as per the National Cancer Grid (NCG) Guidelines:

1) Covering letter stating the purpose

2) Filled application - Form 3-F.

3) Completed Form 3-J which specifies the Annual Requirement of the ENDs (Essential Narcotics Drugs like Morphine, Methadone and Fentanyl) and source(s) for purchase

4) Name of the employed doctor who would be the Officer in-charge and copy of her/his;

a. Medical graduation certificate

b. Certificate of registration

c. Certificate of training in medical use of opioids

5) Self-addressed stamped envelope [Stamp worth ₹ 27/-]

We are very thankful to the Drug Controller for participating in this workshop and assuring his full support to the process of procuring morphine and other opioids.

All institutes can reach out the Pallium India Regional Facilitator – Rajendra Dutt at 9411780217 for any support in filling the application and follow ups with the SDC office.

We are also attaching the following documents with this email for everybody’s reference.

1. Dr. Rajagopal’s presentation

2. Notification regarding exemption of palliative care centres from the need for a pharmacist.

3. National Cancer Grid Guidelines for procuring and stocking opioids

4. Order from the then Secretory General, Shri B. N Sharma

5. Rules of the NDPS Amended Act 2015 by Ministry of Revenue