

Dr. Ebtesam Ahmed, St. John's University Report ECDD Open Meeting, Geneva.

On November 12th I attended the 41st Expert Committee on Drug Dependence open session meeting, which took place in Geneva. I was representing the International Association for Hospice and Palliative Care. The Committee discussed, among other topics, whether or not to recommend that tramadol, an opioid pain medication used to treat moderate to severe pain in many countries, should be listed in one of the schedules of the international drug control conventions. Currently, tramadol is not scheduled, or subject to international control, like morphine or fentanyl, although it is regulated at the national level in many countries worldwide.

The meeting started with Dr. Mariangela Simao, Assistant Director-General for Drug Access, Vaccines, and Pharmaceuticals at the World Health Organization (WHO) who opened the meeting and welcomed participants. Additionally, she provided a statement about the importance of balancing the ethical and public health perspectives when discussing placing certain compounds under international control. She stated the fact that 75% of the world population has no proper access to pain treatment and although morphine is cheap, has no patent, yet it remains readily not available for many countries around the world." Later, Dr. Gilles Forte, Secretary, WHO Expert Committee on Drug Dependence provided an overview of the ECDD committee, which consists of an independent group of experts in the field of drugs and medicines. He emphasized that the ECDD main task is to assess the health risks and benefits of the use of psychoactive substances according to a set of fixed criteria. These criteria are evidence of the dependence potential of the substance, actual abuse and/or evidence of likelihood of abuse and therapeutic applications of the substance. The aim of these recommendations is to ensure that international control measures can effectively protect people's health, in particular, the most vulnerable, but do not limit access to products with proven therapeutic properties.

Christa Cepuch, Pharmacist Coordinator from Medicines San Frontieres (MSF) gave a statement regarding the consequences of scheduling tramadol on an international level and the impact it would have on the palliative care community. She stated that scheduling of tramadol would create two problems first the national system necessities for compliance with international requirements under the drug control trade maybe incomplete or non-functional, this can make it impossible for countries to meet their international obligations effectively shutting doors to legally accessing Tramadol. The

second many countries place unnecessary restrictive controls that go beyond what is internationally required. For example, some countries require multiple physicians to authorize a single prescription for an opioid would only allow certain specialists physician to authorize them or only authorize a small number of pharmacies to dispense them and in small quantities. The consequences to these controls are massive gaps in access whereby over 5 billion people live in countries with little to no access to strong pain medicine and they suffer endlessly in pain. Tramadol is often the sole option for managing moderate to acute pain in MSF programs where no morphine is available. In the last two years, in 2016 and 2017 MSF projects used over 1 million oral and injectable dose of tramadol per year, over 2.4 million doses were sent to their projects in the field. Tramadol is an essential medicine to MSF projects around the world, placing it under international control would leave patients and medical providers with even fewer options. She added “government where tramadol misuse is a problem can take steps to domestic control to ensure an appropriate balance between its restrictions while ensuring its availability for medical use. “

I then had the opportunity to present the data from the recently conducted survey in October 2018 by IAHP to our physicians' members to identify the uses of tramadol for analgesic purposes and the potential impact that the scheduling would have in ensuring access for legitimate medical needs in pain treatment and palliative care. Of the 470 prescribers who responded the survey, 415 stated that they use tramadol for pain treatment. Participants represented providers in 74 countries, of which 134 were located in Lower Middle- and Low-income countries and in all regions of the world. Sixty percent of the participants work in palliative care, while 27% work half-time in pain practice and half-time in palliative care. The remaining 13% see patients suffering from acute and chronic non-malignant pain. Seventy three percent prescribe tramadol daily or at least once a week. Most use it for the treatment of mild to moderate pain (53%) and moderate to severe pain (43.4%). However, 4% of participants from 9 countries use it for all levels of pain, having no other analgesic available. According to the participants, placing tramadol under international control would have a negative impact (100 being “Extremely negative impact on access to pain treatment”). Participants from LIC and LMIC rate a higher negative effect on access to pain treatment if tramadol is placed under international control when compared to participants from High-Income Countries, where other analgesics are available. I also had the opportunity to share some of the comments and feedback we got from the participants. I emphasized from my personal experiences in Guatemala how Tramadol plays an extremely important role in palliative

care and pain relief considering it is one of the very few treatment options available for the management of pain. From a public health and a human right perspective, the consequences of scheduling tramadol would be devastating for patients and medical providers in countries and regions where morphine is not available.

Following me, Dr. Mahmoud Elhabiby, a representative from the Ministry of Health in Egypt gave a presentation about the current situation in Egypt and the public health crisis Egypt is facing with the Tramadol. It was very evident from his presentation that the widespread of illicit Tramadol has become an alarming public health concern for the Egyptian government in recent years. It is important to emphasize that the problem Egypt is having is with illicit substances coming into the countries through illegal ways and not the medical prescription Tramadol.

Christopher Hallam, from International Drug Policy Consortium, gave a statement highlighting that “Tramadol is often the only analgesic medication available for pain options especially in low income and low middle-income countries.”

The last presentation was given by a group of experts representing Grünenthal: Silvia Allende Perez, Instituto Nacional de Cancerologia, Mexico Ernest Yorke, Korle-Bu Teaching Hospital, Ghana Ramani Vijayan Sannasi, University of Malaya, Malaysia Kelly Dunn, Johns Hopkins School of Medicine, USA Axel Klein, ACK Consultants, UK. Axel Klein shared his field research study that was conducted in Botswana and Namibia, where the non-medical use of tramadol or other prescription medicines is largely unknown, and five countries in West Africa. He shared that in the context of this project it was possible to obtain eight samples from the Forensic Police in Niamey, Niger for testing at the laboratories of Grünenthal in Aachen, Germany. The analyses showed that 7 were adulterated with other substances, and did not contain the dosage indicated on the packet. In fact, none of the samples found in West Africa was in compliance with international or national regulations for medical products. He emphasized that the tramadol sold outside of medical establishments is often adulterated and substandard, there is no known licit production of Tramadol in Egypt or anywhere else in Africa, and the bulk of both licit and illicit imports reportedly originate from India and China. He states that strict control does not limit availability and cited in spite of these controls, Egyptians can still find tramadol. One study of 75 patients found that “The new restrictive regulations did not limit access to the trafficked counterfeit tramadol which may harm cancer patients rather than benefiting them” (Alsirafy et al., 2014).

Additionally, Dr. Ernest Yorke from Ghana stated: "Access to pain control is a basic human right, putting Tramadol under international control will increase the use of Non-Steroidal Anti-inflammatory (NSAIDs) and their side effects, not solving the counterfeiting and illicit trafficking." He urged the ECCD committee that we all should act responsibly.

Dr. Silvia Perez reported that currently there is no Tramadol abuse in Latin America and that Tramadol is an important medication for those with moderate to severe pain with chronic conditions.

Dr. Ramani Sannasi from Malaysia stressed the important role Tramadol plays in managing pain in Malaysia considering lack of other strong opioids. She quoted "Although few people die of pain, many die in pain and even more live in pain."

In many parts of the world where many regulatory and administrative barriers exist that obstruct the availability and accessibility of pain medications for millions of patients who suffer endlessly, Tramadol may be the only option available. Tramadol plays such an extremely important role in palliative care and pain relief and placing tramadol under international control would limit access to millions of patients to pain treatment, especially in countries where it is limited or no access to other analgesics. Pain-free is a basic human right, international conventions should work to remove and not raise obstacles towards achieving this.