India urged to reverse dextropropoxyphene ban

Palliative care experts have urged the Indian Ministry of Health to reverse its decision to ban the manufacture and sale of dextropropoxyphene and formulations that contain it. The ban on the cheapest opioid available for oral use could increase the pain burden of patients with cancer who cannot afford costly alternatives.

The ban emanates from a policy change under which drugs banned in specified countries (the USA, the UK, the European Union, Australia, Canada, and Japan) are to be prohibited for sale in India too. The change was effected in December, 2012, after severe criticism of the drug regulation by a parliamentary panel. Another reason for the ban was reported misuse of the drug by addicts in Indian states bordering Burma.

M R Rajagopal (Trivandrum Institute of Palliative Sciences, Thiruvananthapuram, India) said the ban would adversely affect palliative care because availability of morphine was still restricted by strict regulations governing narcotic drugs. "Even if we can address regulatory issues fully, it will take years before morphine becomes available to all the needy", he adds.

Palliative care experts believe that a risk–benefit analysis in the Indian context should have been done instead of copying regulators in developed countries. One of the main reasons for the ban in high-income countries was that the drug was misused as an agent for suicide and when taken with alcohol. In India, suicide agents are completely different. "Other evidence pertains to its misuse as a recreational drug or in multiple drug toxicity, not its use in chronic pain", argues an appeal to the Ministry of Health issued by the Indian Association of Palliative Care and WHO Collaborating Center for Policy and Training on Access to Pain Relief (Thiruvananthapuram, India).

However, other experts suggest that dextropropoxyphene is only a weak analgesic with little use for acute and severe pain of malignancy. "That's why even for moderate pain, it needs to be combined with paracetamol", claimed Chandra M Gulhati (Monthly Index of Medical Specialties, New Delhi, India). "The same argument can be advanced for other analgesics as well because pain is not easily measurable, and good studies are difficult anyway in conditions like advanced malignancy", countered Suresh Kumar (Institute of Palliative Medicine, Calicut, India).

Dinesh C Sharma

Indian Association of Palliative Care

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For more on the **dextropropoxyphene ban** see http://www.livemint.com/Politics/FPzokZX4LhkTrTrvb7knPL/Govt-bans-pain-killer-drug-dextropropoxyphene.html

Lenalidomide as first-line therapy for elderly CLL patients

Two-thirds of all patients who are newly diagnosed with chronic lymphocytic leukaemia (CLL) are older than 65 years, but these individuals are infrequently represented in clinical trials. No consensus exists on the best first-line therapy for CLL in elderly patients, a population who often experience treatment-limiting toxicities with the therapeutic regimens that are effective in younger patients.

A recent single-group phase 2 clinical trial studied single-agent lenalidomide as initial therapy for symptomatic CLL in treatment-naive patients older than 65 years (median age 71 years). The investigators reported that long-lasting responses were induced by long-term treatment with this oral immunomodulatory agent with continuous daily dosing at a median of 5 mg. After a median follow-up of 4 years, overall survival was 82% in the 60 patients enrolled in the study, and 35 (58%) of the participants were long-term responders, whose response lasted longer than 36 months. Median time to treatment failure had not yet been reached.

All long-term responders experienced neutropenia, with 12 patients having grade 3–4 severity during the first 12 months of treatment. However, this was resolved in 29 of the 35 patients (including all grade 3–4), mostly through dose reduction.

"In CLL, it's very important to show how durable the treatment is", said senior author Alessandra Ferrajoli (The University of Texas MD Anderson Cancer Center, Houston, TX, USA). With this study, "the patients had responses to lenalidomide that were durable, there was a good survival rate, and the benefit of increases in immunoglobulin levels was maintained."

Ferrajoli added that studies are ongoing, including "a large, global trial currently comparing single-agent lenalidomide to a more conservative standard therapy in elderly patients".

"I am thrilled with this publication", Nicole Lamanna (Columbia University Medical Center, New York, NY, USA) told *The Lancet Oncology*. "For older patients with CLL, often we would like to avoid aggressive chemotherapy as the treatment is often too myelosuppressive and immunosuppressive. Lenalidomide is an oral therapy, and toxicities are much less than seen with traditional chemotherapies. This is an alternate approach we can offer older patients with CLL who cannot tolerate more traditional regimens. This study has shown that for patients on long-term therapy their response can improve the longer they continue therapy."

Judith A Gilbert

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For the **study** see *Blood* 2013; published online June 25. http://bloodjournal.hematologylibrary.org/content/early/2013/06/25/blood-2013-04-495341