



Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

**GPP
Pharmacist
Competition-
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Editorial

Practice in Pharmacy is existing in India since long back, with a different name and structure and it has got a regulated structure since implementation of Pharmacy Act 1948. Engagement of Pharmacist in serving the prescription of a registered practitioner has been made mandatory by an amendment of sec 42 of Pharmacy Act 1940, in the year of 1984 and it was further bolstered by the amendment of Rule 65 of Drugs and Cosmetics Rules 1945 in the same year. Publication of "The Role of the Pharmacist in the Health Care System" by World Health Organization in the year of 1990 has given a solid platform to create more conducive environment for growing Pharmacy Practice in India. Dispensing by pharmacists is mandatory worldwide for better health care services.

Framing and notification of Pharmacy Practice Regulation 2015 in the month of January 2015 is a landmark event in the history of Pharmaceutical Profession in India, which will certainly help in giving proper shape to the unorganized state of Pharmacy Practice in India. In the present regulation the Pharmacy Practice is well defined and the same has set up certain regulation to regulate the same.

In order to implement this regulation in letter and spirit it is essential to upgrade knowledge of the pharmacists and D.Pharm. Pharmacists should be given opportunity to upgrade them through pursuing B.Pharm. Pharmacy Practice Course. In some states it has already been started but in some states it is yet to be started. Therefore all state governments and Universities require to be proactive to start B.Pharm. Pharmacy Practice Courses considering the societal need for improving health care system.



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New Drug: Tafenoquine succinate for malaria prevention

Approved indication in Australia: Malaria prevention
Kodatef (Biocelect)
100 mg tablets

Tafenoquine, a primaquine analogue, is indicated for prophylaxis against malaria in adults. It is a long-acting 8-aminoquinoline that is active at all stages of the malaria life cycle, including the liver stage where the parasites can lie dormant (as hepatic hypnozoites) before entering the bloodstream. This usually occurs less than a month after the initial infection but relapse can be delayed by several years.

It is not clear how tafenoquine kills the parasite but it has been shown to be effective in preventing infection with *Plasmodium falciparum* and *P. vivax* in people living in malaria-endemic regions.¹⁻⁴ Its approval in Australia is based on a comparative trial with mefloquine in healthy non-immune Australian soldiers (n=654) deployed to Timor-Leste.⁵

Soldiers were randomised 3:1 to tafenoquine 200 mg or mefloquine 250 mg. After a loading phase of a single dose per day for three days, soldiers entered the prophylactic phase in which they received a dose once a week for 26 weeks (\pm 4 weeks). On returning to Australia, soldiers entered the relapse follow-up phase where those in the mefloquine group received primaquine (15 mg twice a day) for 14 days while those in the tafenoquine group received a corresponding placebo. There were no malarial infections during the prophylactic phase with either treatment. However, during the relapse follow-up phase, there were four cases of *P. vivax* in the tafenoquine/placebo arm (4/462, 0.9%) and one case in the mefloquine/ primaquine arm (1/153, 0.7%).⁵ These occurred 16–20 weeks after returning from Timor-Leste.

In a safety cohort of 825 people, there were 23 serious adverse events that were thought to be related to tafenoquine treatment. These included eye disorders (7 cases), decreased glomerular filtration rate (5 cases), infection (4 cases) and gastrointestinal disorders (4 cases). The most common adverse events that led to

discontinuation were increased liver enzymes, decreased haemoglobin and decreased glomerular filtration rate.

In an ophthalmic assessment of a subgroup of soldiers in the Timor-Leste study, 93.2% (69/74) had vortex keratopathy (corneal deposits) by the end of the prophylactic phase. This did not seem to affect their vision and all cases had resolved after a year.⁵

Like primaquine, tafenoquine can induce haemolytic anaemia in people with glucose-6-phosphate dehydrogenase (G6PD) deficiency. This is especially a concern because tafenoquine has a very long half-life of 17 days. Tafenoquine is contraindicated in G6PD deficiency and in pregnancy and lactation as the G6PD status of the infant is unlikely to be known.

Although not teratogenic in animal studies, tafenoquine caused dose-related abortions in pregnant rabbits. Women of childbearing age should use contraception while taking tafenoquine and for three months after finishing prophylaxis. This drug has not been tested in children.

Tafenoquine is also contraindicated in people with current or a history of psychosis, delusions or hallucinations. Even though people with a history of psychiatric disorders were excluded from the Timor-Leste trial, sleep disturbance, depression or depressed mood and anxiety were increased. One person attempted suicide.

Following a single oral dose of tafenoquine, maximum plasma concentrations are reached after seven hours. The drug's half-life is 17 days. Tafenoquine should not be taken for longer than six months. The treatment course should include a 3-day loading dose before travel, weekly dosing while away and a single dose on return. The gastrointestinal effects of tafenoquine may be reduced by taking tablets with food. Dose adjustment in renal and hepatic impairment has not been studied.

Tafenoquine may inhibit drug transporters in the kidney which could lead to increased concentrations of renally excreted drugs. If tafenoquine is co-administered with drugs (e.g. dapsone) that have the potential to cause haemolysis in people with normal G6PD function,

they should monitor their urine for dark colour and have their haematocrit checked.

Tafenoquine seemed to be as effective as mefloquine/ primaquine at preventing malaria during prolonged stays in a malaria-endemic region. However, it can cause severe haemolytic anaemia and everyone must be tested to make sure they do not have G6PD deficiency before being prescribed this drug. Tafenoquine's once-weekly dosing may be preferred by some travellers.

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Note: This drug is yet to be launched in India.

Code prohibits Doctors from taking gifts from pharma companies: Harsh Vardhan, Union Health Minister

Union Health Minister Harsh Vardhan Friday [said](#) in connection to Unstarred Question No. 3306 that the code of conduct for medical practitioners prohibits doctors from taking gifts, travel facilities, hospitality or cash from pharmaceutical and allied health sector industry.

Vardhan also said in Lok Sabha that the government has received some complaints of unethical marketing practices by pharmaceutical companies and the CEOs of such companies will be held responsible for such malpractices.

The minister said the code of conduct for doctors in their relationship with pharmaceutical and allied sector industry of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002 prohibits doctors from taking gifts, travel facilities, hospitality and cash or monetary grants from pharmaceutical and allied health sector industry. The said regulation empowers the Medical Council of India and respective State Medical Councils to award punishment to a doctor against any act in violation of code of Ethics for doctors, he said during Question Hour.

Vardhan said such complaints are referred by MCI to the State Medical Councils concerned where doctors and medical practitioners are registered. The MCI is an Appellate Authority. The minister said the Department of Pharmaceuticals has received some complaints of unethical marketing practices by pharmaceutical companies.

Vardhan said as informed by Department of Pharmaceuticals, the complaints received are forwarded to Pharma Associations concerned for necessary action as per provisions of Uniform Code for Pharmaceutical Marketing Practices (UCPMP), as prepared by Department of Pharmaceuticals. The Managing Director or CEO of the pharma company is ultimately responsible for ensuring adherence to the code, he said.

Source: Free Press Journal

Homeopathy doctor administrating allopathic medicines is medical negligence: NCDRC

A homoeopathic doctor is not qualified to prescribe allopathic medicines and will be liable for medical negligence and will have to pay compensation if a patient suffers from medical complications, the National Consumer Disputes Redressal Commission (NCDRC) has ruled.

The ruling by the apex consumer commission came almost two decades after a woman in Nagpur died soon after a homoeopathy doctor

gave injections to her for her stomach pains. The commission directed the doctor to pay compensation of Rs 10 lakh to her family members, stating that he is a diploma holder in homoeopathy and is not qualified to practise allopathy.

The incident took place in 2000 when the woman was taken to the doctor by her family members after she complained of stomach pain. The doctor gave two injections —Baralgan and Dexamethasone. Immediately after the injections, the woman felt uneasy and died. The post-mortem report attributed the death to anaphylactic reaction caused by the injections.

Holding the doctor guilty of medical negligence, a bench of Dr S M Kantikar and Dinesh Singh said the doctor is a diploma holder in homoeopathy and is unqualified to practise allopathy, and liable for medical negligence. It upheld the state consumer commission order holding the doctor guilty but increased the amount of compensation from Rs. three lakh to Rs. 10 lakh and granted him four weeks' time to pay the money.

“It is clear that the opposite party (doctor), being a homoeopathic practitioner, is not having any authority to administer allopathic medicines i.e. injections. Thus, without any authority he

administered the said injections of allopathic medicines and as her (patient's) death was caused due to reaction of the said injections, it proves negligence on his part,” the NCDRC said.

The commission rejected the plea of the doctor who contended that he should not be liable for negligence as he has been acquitted in the criminal case lodged by deceased's family.

“Liability for a civil wrong and liability for a criminal offence are different. The objective of criminal law is to punish, the objective of civil law is to compensate, they essentially differ in their context and consequence. The two are not mutually exclusive, but co-extensive,” it said.

The NCDRC said, “Considering the case in its entirety, and, specifically, that the death of the patient occurred in 2000, and we are now in 2019, and the patient died at a young age (in her 20's), and left behind her husband and (as of then) two minor children, though it is difficult to quantify life in monetary terms, in our considered view, compensation of Rs 10 lakh with simple interest at 12% per annum from the date of arguments before this Commission from October 2018 would be just and equitable in the totality of the facts and specificities of the case.”

Source: The Times of India



Pharmacist Day 2019

GPP Pharmacist Competition

Competition for Community Pharmacists

Greetings from Indian Pharmaceutical Association-Community Pharmacy Division (IPA CPD). World Pharmacist Day 25th September is fast approaching. IPA CPD is pleased to announce a competition for community pharmacists. Objective of this competition is to identify and felicitate those pharmacists across the country who are trying to implement Good Pharmacy Practices in their pharmacies.

In 1992, the International Pharmaceutical Federation (FIP) developed standards for pharmacy services under the heading "Good Pharmacy Practice in community and hospital pharmacy settings". This was further endorsed by the WHO in 1997. The Indian Pharmaceutical Association (IPA) developed GPP Guidelines for India in 2002, and followed it up with a GPP Training Manual in 2005, in collaboration with WHO India Country Office and the Central Drugs Standards Control Organisation.

The mission of pharmacy practice is to contribute to health improvement and to help patients with health problems to make the best use of their medicines.

Eligibility for participation:
A community pharmacist from independent pharmacies in India, with a minimum of 10 years of experience in community pharmacy.

Submit entries at:
<https://tinyurl.com/y2ia9puo>
before August 10, 2019

Shortlisted pharmacists will be contacted and the pharmacies will be visited by experts. Winners will be announced by September 25, 2019; will be rewarded with cash award and a set of IPA publications. Each participant will be given a certificate of participation.

INDIAN PHARMACEUTICAL ASSOCIATION
www.ipapharma.org

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