Drug Information Bulletin

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Content

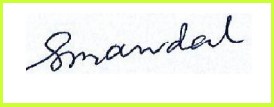
Editorial

To curb misleading advertisements and false claims Govt. of India has published draft notification amending Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 increasing punishment.

In the proposed amended act punishment increased up to 2 year imprisonment and fine up to RS. 10 lakh for first time offender and up to 5 years imprisonment and fine up to Rs 50 lakh for subsequent offence. Number of diseases enlisted was increased to 78 from 54.

Presently there are so many advertisement appears in the print and electronic media claiming to make skin fairer, increase hight, grow hair, increase vigor even cure HIV, Cancer etc. as the earlier form of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 have insufficient measures to curb it.

Experts feel that the Drugs and Magic Remedies (Objectionable advertisement) Act was framed in the year of 1954, which fails to prevent misleading advertisement and false claims. They also feel that this amendment was overdue to protect the general people and extended welcome to the proposed amendment.



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How can Pharmacists advise about Corona virus: FIP

CORONAVIRUS 2019-nCoV
HOW CAN PHARMACISTS ADVISE?

No symptoms (cough, fever or breathing difficulties)

No travel history to affected areas or contact with infected people

- Offer reassurance
- Very unlikely to have 2019-nCoV infection risk
- Highlight preventive measures
- Provide evidence-based information and advice (oral and/or written)

Symptoms (cough, fever or breathing difficulties)

No travel history to affected areas or contact with infected people

- Offer reassurance
- Unlikely to have 2019-nCoV infection risk
- Highlight preventive measures
- Provide evidence-based information and advice (oral and/or written)

No symptoms (cough, fever or breathing difficulties)

Recent travel history to affected areas or contact with infected people

- Offer reassurance
- Risk of 2019-nCoV infection may exist
- Highlight preventive measures and recommend home quarantine for 14 days
- Trace contacts history
- Provide evidence-based information and advice (oral and/or written)
- In case symptoms appear in the 14 days following return from travel or contact with infected person, contact emergency number or reference hospital

Travel plans to affected areas or contact with infected people

- Offer reassurance
- Risk of 2019-nCoV infection may exist
- Recommend home quarantine for 14 days upon return from travel
- Inform about the situation and ways of transmission
- Highlight preventive measures
- Provide evidence-based information and advice (oral and/or written)

Symptoms (cough, fever or breathing difficulties)

Recent travel history to affected areas or contact with infected people

- Offer reassurance
- Risk of 2019-NCoV infection may exist
- Contact health authorities to initiate care protocol
- Inform about the procedure of isolation, diagnosis and treatment
- Highlight measures to prevent further transmission
- Provide evidence-based information and advice (oral and/or written)

Adapted from "Coronavirus 2019-nCoV: Intervenção da farmácia", Associação Nacional das Farmácias (Portugal)

fip ADVANCING PHARMACY WORLDWIDE

More information:
www.fip.org/coronavirus

Medical Devices Trade Margins Likely To Be Capped At 30%

A cap on trade margins at 30% for medical devices is being considered, as India and US move ahead to sign a mutually acceptable trade deal this month, people in the know said.

The government seems to have found a middle ground between demands of the domestic industry and global MNCs investment. While it has decided to abandon the price cap regime for medical devices (as in the case of stents and knee implants), a limit of 30% trade margin on medical devices is likely to be approved soon, the same people said.

A series of meetings were held between drug pricing regulator National Pharmaceutical Pricing Authority (NPPA), Niti Aayog, Department of Pharmaceuticals (DoP) and the ministry of commerce over the last few days and "the government is likely to replicate the formula it applied for reducing cancer drug prices, which means capping trade margins at 30%," said one of the persons.

The government had, in February 2019, slashed cancer drug prices, indicating the move is a pilot for more drugs and medical devices. "This is being rolled out as a pilot for the proof of concept, which means that it will be upscaled," NPPA chairperson Shubhra Singh had said then. The issue of first point of sale for domestic producers and multinationals is a concern, and is yet to be decided upon, said the person quoted above, requesting anonymity.

The government is of the view that the maximum retail price (MRP) of a device should be decided by adding the trade margin to the price at the first point of sale (stockist). However, "The work is in progress. We have to take a balanced view and seen that the formula used for cancer drugs have slashed prices tremendously without hurting the industry. The first point of sale is yet to be decided", added another person. The trade margin is the difference between the price at which the manufacturers/importers sell to stockists and the price charged to consumers.

With this, the government seeks to abandon the current price control mechanism, as it allays the concerns of device makers, particularly importers of stents and knee implants, who have complained that price caps hurt innovation.

Currently, only 23 medical devices have been notified as drugs and are regulated under the Drugs and Cosmetics Act. Of these, only four—cardiac stents, drug-eluting stents, condoms and intra-uterine devices—are included in the National List of Essential Medicines and are, therefore, subject to notified price caps. Stents and knee implants were the latest to be brought under the price control under para 19 of the Drugs (Price Control) Order, 2013. The remaining medical devices are not under any form of price regulation.

Sources said India's price control regime on medical devices was a key obstacle in trade deal pegged above $10 billion (more than Rs 70,000 crore). The government's earlier move of price control on stents had become a contentious issue between the two countries. It led to a price cut of up to 85% resulting in many MNCs withdrawing their products from the country.

The US has since then been pressing India not to extend price caps on other medical devices.

US trade representative Robert E Lighthizer will be in India in the second week of February to finalise the trade deal.

Source: Economic Times

Govt Asks Pharma Cos To Stick To Marketing Norms Amid Allegations Of Bribery

At a time when allegations of doctors being bribed with foreign trips and gifts have rocked the pharmaceutical industry, the government has asked drug makers and their associations to adhere to current guidelines for marketing drugs.

"Pharma associations are requested to make sure that the pharma companies adhere to the provisions of the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) and no unethical promotion of pharma products is done during such conferences," the Department of Pharmaceuticals (DoP) wrote to industry associations. Mint has reviewed a copy of the letter dated 4 February.

The government's letter comes amid increasing clamour from various parties for reviewing guidelines for pharmaceutical marketing over allegations that companies, in a bid to make

doctors prescribe their medicines more often, are bribing doctors with foreign trips, gifts, gadgets and even women.

The government is currently reviewing the UCPMP and has met pharmaceutical companies, an official said.

“The first meeting to review the guidelines was held a few weeks back, and we will be calling the next meeting soon. In the first meeting, we could make out that none of the associations were strictly complying with the UCPMP, so we have instructed them to do so," an official at the DoP told Mint, on condition of anonymity.

The UCPMP is a voluntary code for ethical marketing of pharmaceutical products, under which pharmaceutical companies and their sales representatives are barred from giving gifts and free trips to doctors. Even if a doctor goes for a conference, they will have to do so at their own cost, as per the code.

“Rather than taking steps to instituting statutory regulation of unethical marketing and promotion, DOP is still requesting companies to abide by a toothless, unenforceable UCPMP. Given that all stakeholders now--including various industry associations, IMA and doctors bodies, civil society and patients groups--are in agreement about bringing in a regulation, we cannot understand why DOP is refusing to do so," Malini Aisola, co-convenor of All India Drug Action Network, told Mint.

Aisola said the DoP should immediately implement a mandatory mechanism for company disclosure of payments towards doctors and professional bodies, including through third parties. These disclosures should be made at intervals and put in public domain, and should include the amount spent, individual or entity to which payment was made and the reason for payment including any services rendered, she said.

pharmaceutical companies bribe doctors with various gifts, ranging from pens and pen stand to Apple phones costing ₹80,000 and X-ray equipment for the clinic.

“Some doctors who give huge business demand women for entertainment and these demands are met," the report had said.

The report also said that companies and their representatives would push allopathic products even to doctors practising Ayurveda and other alternate medicines.

SATHI’s report sparked considerable outrage, with Prime Minister Narendra Modi asking pharmaceutical companies in a meeting to not give gifts to doctors.

However, the Indian Medical Association, an organization of over 3 lakh doctors, wrote to PM Modi seeking clarification over his comments which they alleged were based on unverified information.

Source: livemint

Rare pediatric disease status granted to gene therapy for sickle cell disease

Aruvant's gene therapy candidate ARU-1801 was granted the FDA's rare pediatric disease designation as a treatment for blood disorders such as sickle cell disease and beta-thalassemia. "Our Reduced Intensity Conditioning (RIC) approach aims to provide patients a cure with an improved risk-benefit profile, including a lower risk of infertility and fewer days in the hospital," said Aruvant CEO Dr. Will Chou.

Ref. Sickle Cell Anemia News