There are a huge number of complaints against the advertisement of Drugs and Medicines are being noted in the public media in recent times, which shows the awareness of the general people. But they are not aware about the existing legislations effective in India to regulate advertisement on Drugs and Medicines. Earlier the advertisement of drugs and medicines were regulated by the Drugs and Magic Remedies (Misleading advertisement) Act 1955, which was considered as a week regulation as penal provisions are not strong. Considering this fact Govt. of India has taken an initiative to amend the said act a few years back in which is covers amendment of schedule of ailments and introduced stringent penal provisions, but till the amended version is not notified. In the mean time the Drugs and Cosmetics Rules has been amended to prohibit the advertisement of Schedule H, Schedule H1 and Schedule X drugs since 15<sup>th</sup> April 2015.

Though this amendment is effective in India since 15<sup>th</sup> April 2015, so many advertisements are being seen in public media. Implementing authority needs to be more vigilant and should take actions as per the law.
An interesting amendment of The Drugs and Cosmetics Rules to prohibit advertisement of Schedule-H, Schedule-H1 and Schedule-X drugs in India with effect from 15th April 2015

MINISTRY OF HEALTH AND FAMILY WELFARE
(Deptartment of Health and Family Welfare)

NOTIFICATION
New Delhi, the 15th April, 2015

G.S.R. 289(E).—Whereas certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published vide notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare vide number G.S.R. 176(E), dated the 11th March, 2014, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 18th March, 2014;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government,

Now, therefore, in exercise of the powers conferred by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:

1. (1) These rules may be called the Drugs and Cosmetics (Third Amendment) Rules, 2015.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945,—

(i) in rule 74, after clause (o), the following clause shall be inserted, namely:—

“(p) No advertisement of the drugs specified in Schedule H, Schedule H1 and Schedule X shall be made except with the previous sanction of the Central Government.”;

(ii) in rule 74A, after clause (h), the following clause shall be inserted, namely:—

“(i) No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government.”;

(iii) in rule 74B, after clause (6), the following clause shall be inserted, namely:—

“(7) No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government.”;

(iv) in rule 78, after clause (p), the following clause shall be inserted, namely:—

“(q) No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government.”;

(v) in rule 78A, after clause (7), the following clause shall be inserted, namely:—

“(8) No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government.”.

[F. No. X-11014/3/2012-DFQC]

K. L. SHARMA, Jt. Secy.

Note.—The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1) dated the 21st December, 1945 and last amended vide notification number G.S.R. 203 (E) dated the 18th March, 2015.
Meta-analysis suggests pre-existing mental disorders associated with increased risk of COVID-19 mortality

Pre-existing mental disorders, in particular psychotic and mood disorders, and exposure to antipsychotics and anxiolytics were associated with coronavirus disease 2019 (COVID-19) mortality, according to a meta-analysis published in The Lancet Psychiatry.

“We identified strong evidence that patients with mental disorders are at higher risk of mortality and hospitalisation, but not intensive care unit (ICU) admission, after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Patients with substance use disorders were at increased risk of hospitalisation, whereas no increased risk of hospitalisation was identified among patients with psychotic disorders,” reported Benedetta Vai, IRCCS San Raffaele Scientific Institute, Milan, Italy, and colleagues.

“Our findings show marked differentiation in COVID-19 outcomes among different mental disorders.”

“Mental disorders might be a risk factor for severe COVID-19. We aimed to assess the specific risks of COVID-19-related mortality, hospitalisation, and ICU admission associated with any pre-existing mental disorder, and specific diagnostic categories of mental disorders, and exposure to psychopharmacological drug classes,” the researchers noted.

The meta-analysis included 23 studies, comprising 1,469,731 patients with COVID-19, of whom 43,938 had mental disorders. Overall, the researchers observed that the presence of any mental disorder was associated with an increased risk of COVID-19 mortality (odds ratio [OR] 2.00, 95% confidence interval [CI] 1.58–2.54, I² = 92.66%). In sensitivity analyses, all results remained statistically significant, suggesting consistent effects across samples and models.

When stratifying mortality risk by psychiatric disorder type, the association with mortality risk was also observed for psychotic disorders (OR 2.05, 95% CI 1.37–3.06, I² = 80.81%), mood disorders (1.99 [1.46–2.71], I² =68.32%), substance use disorders (1.76 [1.27–2.44], I² = 47.90%), and intellectual disabilities and developmental disorders (1.73 [1.29–2.31], I² = 90.15%) but not for anxiety disorders (1.07 [0.73–1.56], I² =11.05%). In addition, COVID-19 mortality was associated with exposure to antipsychotics (3.71 [1.74–7.91], I² = 90.31%), anxiolytics (2.58 [1.22–5.44], I² =96.42%), and antidepressants (2.23 [1.06–4.71], I² = 95.45%). For psychotic disorders, mood disorders, antipsychotics, and anxiolytics, the association remained significant after adjustment for age, sex, and other confounders. Further, mental disorders were associated with increased risk of hospitalisation (OR 2.24, 95% CI 1.70–2.94, I² = 88.80%). After stratification by disorder, the most robust association with hospitalisation was identified in patients with a comorbid substance use disorder (2.66 [1.79–3.95], I² = 91.31%), whereas psychotic disorders were not significantly associated with hospitalisation (1.68 [0.86–3.29], I² = 57.62%). Meanwhile, the association between mood disorders and hospitalisation after SARS-CoV-2 infection was significant on the basis of the crude estimate (OR 2.26 [1.33–3.86], I² =87.9%) but not the adjusted estimate (adjusted OR [a OR] 1.26 [0.64–2.50], I² =23.09%). On the other hand, the researchers found no robust evidence of an increased risk of ICU admission for patients with mental disorders (OR 1.77 [1.09–2.89]; a OR 1.33 [0.87–2.04]).

“In conclusion, pre-existing mental disorders, in particular severe mental illness, intellectual disability, and substance use disorders, and previous exposure to psychopharmacological compounds were associated with poor COVID-19 outcomes,” the authors noted. “Public health authorities should consider priority vaccination for all groups of at-risk patients identified in this study.”

“Similar to a previously published meta-analysis, overall heterogeneity in this analysis was high, and was substantially reduced in adjusted estimates and after stratification for mental disorders, pharmacological treatments, baseline COVID-19 treatment setting, and country. This confirms the relevance of these variables in affecting COVID-19 outcomes,” the authors added.
DCGI Classifies 112 Anesthesiology Devices Under Medical Devices Rules

On 16th July 2016 The Drug Controller General (India) has classified 112 medical devices related to anesthesiology, which is used in taking care of a patient before, during and after surgery, under Medical Devices Rules.

The devices including pulse oximeter, anesthesia machine, tracheostomy kit, oxygen, air and nitrous oxide breathing gas mixer, and epidural anaesthesia kit have been classified under risk class C. It may be noted that the government had earlier this week announced capping of trade margins for five medical devices including pulse oximeter.

Aerosol face mask, aerosol inhalation monitor, airway pressure or oxygen monitor device among others have been classified under risk class B. Devices including anaesthesia catheter Luer connector, anaesthesia depth simulator, anaesthesia instrument table and others have been classified under risk class A.

Risk Class A is considered as lower risk, while Class B is low moderate risk and Class C is moderate high risk. The classification is based on the intended use of the device, risk associated with the device and other parameters specified under the Medical Devices Rules, 2017.

Of the devices classified under the new notice, almost 49 are under Risk Class A, and around 45 are under Risk Class B, while the rest are under Class C.

Accessories and components of medical devices imported as a system need not be registered separately. However, this does not debar from risk based classification of the accessories or components of medical devices, it said.

The anaesthetics and catheters of cardio respiratory devices manufacturing is supported by the Department of Pharmaceuticals under production linked incentive (PLI) scheme to boost domestic manufacturing.

The Central Drugs Standard Control Organisation (CDSCO) had earlier this month updated the list of medical device testing laboratories registered with the regulator to 14 across the country. There are more applicants which are under evaluation, said CDSCO.

Source: Pharmabiz