DRUGS & COSMETICS

-COPY OF-
NOTIFICATION
Dated 30th August, 2013

Whereas certain draft rules further to amend the Drugs and Cosmetics Rules, 1945, were published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), without consulting the Drugs Technical Advisory Board vide notification of the Government of India, Ministry of Health and Family Welfare (Department of Health/and Family Welfare), number G.S.R.228(E), dated the 20th March, 2012, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 20th March, 2012, 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 containing the said notification were made available to the public;

And whereas the copies of the Gazette in which the said notification was published were made available to the public on the 20th March, 2012;

And whereas, the Drugs Technical Advisory Board has been consulted in the matter,

And whereas, objections and suggestions received in respect of the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 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 (Fourth Amendment) Rules, 2013.**

(2) They shall come into force after six months of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as said rules),-

(i) in rule 65,-

(a) in condition (3), in clause (1),-

(A) in sub-clause (f) and in item (ii) of the third proviso to sub-clause (g), for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall respectively be substituted;

(B) after clause (g) and the provisos thereof, the following shall be inserted, namely:-

"(h) the supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.

(b) in condition (9), in clauses (a) and (b), for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall respectively be substituted;

(c) in condition (11), for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall be substituted;

(d) in condition (11A), for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall be substituted;

(ii) in rule 97, in sub rule (1), after clause (d), the following shall be inserted, namely,-

'(e) if it contains a drug substance specified in Schedule H1, the drug formulation shall be labelled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label, and shall also be labelled with the following words in a box with a red border:

... / 2

"SCHEDULE H1 DRUG - WARNING:
-It is dangerous to take this preparation except in accordance with the medical advice.

-Not to be sold by retail without the prescription of a Registered Medical Practitioner." ';

3. In the said rules, in Schedule H, the following entries shall be omitted, namely:-

"1. Alprazolam
2. Cefdinir
3. Cefepime Hydrochloride
4. Cefetamet Pivoxil
5. Cefpirome
6. Cefpodoxime Poxetil
7. Ceftazidime Pentahydrate
8. Ceftizoxime Sodium
9. Chlordiazepoxide
10. Clofazimine
11. Codeine
12. Diazepam
13. Diphenoxylate and its salts
14. Ethambutol Hydrochloride
15. Ethionamide
16. Levofloxacin
17. Meropenam
18. Midazolam
19. Moxifloxacin
20.Nitrazepam
21. Pentazocine
22. Pyrazinamide
23. Sparfloxacin
24. Thiacetazone
25. Tramadol hydrochloride
26. Zolpidem";

4. In the said rules, after Schedule H, the following Schedule shall be inserted, namely:-

"Schedule H1
(See rules 65 and 97)

1. Alprazolam
2. Balofloxacin
3. Buprenorphine
4. Capreomycin
5. Cefdinir
6. Cefditoren
7. Cefepime
8. Cefetamet
9. Cefixime
10. Cefoperazone
11. Cefotaxime
12. Cefpirome
13. Cefpodoxime
14. Ceftazidime
15. Ceftibuten
16. Ceftizoxime
17. Ceftriaxone
18. Chlordiazepoxide
19. Clofazimine
20. Codeine
21. Cycloserine
22. Diazepam
23. Diphenoxylate
24. Doripenem
25. Ertapenem
26. Ethambutol Hydrochloride
27. Ethionamide
28. Feropenem
29. Gemifloxacin
30. Imipenem
31. Isoniazid
32. Levofloxacin
33. Meropenem
34. Midazolam
35. Moxifloxacin
36. Nitrazepam
37. Pentazocine
38. Prulifloxacin
39. Pyrazinamide
40. Rifabutin
41. Rifampicin
42. Sodium Para-aminosalicylate
43. Sparfloxacin
44. Thiacetazone
45. Tramadol
46. Zolpidem

Note.- Preparations containing the above drug substances and their salts excluding those intended for topical or external use (except ophthalmic and ear or nose preparations) containing above substances are also covered by this Schedule.".

Sd/-
(Arun K. Panda)
Jt. Secy.

G.S.R.588(E)
F.No.X-11014/6/2010-DFQC
Issued by:
Ministry of Health and Family Welfare
(Department of Health and Family Welfare)
New Delhi

Foot note: The principal rules were published in the Official Gazette vide notification No.F.28-10/45-H (1), dated 21st December, 1945 and last amended vide notification number G.S.R.72(E), dated the 8th February, 2013.

** ** **