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H1 schedule-the review

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ABSTRACT
Schedule H1 are Created and Modified in Drug& Cosmetic Act 1945 From 1 Mar 2014.It has Anticipated For Some Time Bur Now that it is in Force, Needs Wide Publicity and a Critical Look ,From all Physicians and Healthcare Providers in General and the Community of Pharmacologist and Pharmacists,Irrational Prescribing of Antibiotics and Other Drugs by Doctors and Chemists.Lacking a registered Pharmacist has Contributed to the Increasing Antibiotics Resistance and Tolerance of Psychotropics.Therefore Schedule H1 Drug Includes 3rd& 4th Generation antibiotics,Anti-tuberculosis drugs and Certain Habit Forming Drugs Like Psychotropic Drugs.

I. INTRODUCTION

The Schedule H1 notification of the Government of India on Aug 30, 2013, as an amendment to the Drugs and Cosmetics Rules of 1945, has now come into force from Mar 1, 2014. This schedule imposes certain conditions in the dispensing of listed medicines, which are somewhat midway between Schedule H (that stipulates retail dispensing only against a valid prescription) and Schedule X (that stipulates prescription in duplicate, separate license requirement and meticulous storage and dispensing records). This schedule has been anticipated for some time but now that it is in force, needs wide publicity and a critical look, from all physicians and healthcare providers in general and the community of pharmacologists and pharmacists in particular.

The schedule is primarily intended to control the rampant use (that probably includes a large component of misuse through over-the-counter (OTC) dispensing) of antibiotics in India. This intention is laudable. It is an open secret that practically any drug is OTC in India and can be procured in small or large quantities if one knows the right retailers and distributors. People who are below the poverty line, and even those who are not so, prefer to approach friendly neighborhood retailers for minor symptoms, who are more than ready to oblige by handing over small quantities of various drugs, including supply of antibiotics for 2-3 days, for immediate symptom relief. This, we assume, is done in good faith but the long-term consequences are anybody's guess. Easy availability coupled with irrational prescribing of antibiotics by doctors at all levels is contributing to increasing resistance to antibiotics and increasing drug resistant TB cases in India.

What are the immediate implications of the Schedule H1 restriction? Currently, 46 drugs have been placed under this restricted category, which mainly comprises third and fourth generation cephalosporins, carbapenems, newer fluoroquinolones and first- and second-line antitubercular drugs. The packaging of these drugs will have mandatory Schedule H1 warning printed on the label in a box with red border and the Rx symbol in red. They can be sold by pharmaceutical chemists only on production of a valid prescription. The chemist will maintain a separate register where identity of the patient, contact details of the prescribing doctor and the name and dispensed quantity of the drug will be recorded. This register has to be retained for at least three years. The drugs control authority has the responsibility to enforce the order. Government drug inspectors can conduct surprise checks on these registers and monitor sale of these 46 drugs under Schedule H1.

Will this restriction work in dampening rampant OTC sale of antibiotics? Let us hope that the awareness, which this legal provision generates will have a deterrent effect in itself. Schedule X has worked, possibly because the need for duplicate prescription and stringent records makes both prescribers and dispensers wary. But, then Schedule X includes only a handful of drugs that are either obsolete or seldom needed anyway. Schedule H has been there for ages but has not worked efficiently, necessitating a schedule H1 now. What about its enforceability? Inspectors can

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only check what is recorded. How will they check sales that are not recorded in the H1 register, including sales against 'prescriptions' made out by unqualified 'doctors' and 'alternative medicine' practitioners. To do this would mean more elaborate and time consuming cross-checking of the inventory. It is not clear whether the chemist will retain a copy of the prescription that is served. The penal provisions for violation are also not clear.

What are the broader implications of Schedule H1? Will it have any impact on antibiotic resistance? It is still too early to say. The list of 46 items includes 11 that are non-antimicrobials. Therefore, the focus on antibiotics is somewhat diluted. With antibiotics, there are notable exclusions like gentamicin, piperacillin-tazobactam, linezolid and tigecycline. We do not know the reasons for these exceptions – whether the technical advisory committee has not recommended their inclusion or whether market data suggests that their OTC use is non-existent. The older fluoroquinolones, like ciprofloxacin and ofloxacin, have not been restricted, which can be a lacuna because cross-resistance is so common among the bacteria resistant to fluoroquinolones. Older beta-lactams (e.g. co-amoxiclav, cephalexin, cefadroxil) and macrolides (e.g. azithromycin, roxithromycin) have not been included. While this will come as a relief to scrupulous chemists who intend to follow these regulations, their misuse, which is already probably high, may increase. The non-antimicrobial items include opioids, benzodiazepines and zolpidem. Notable exclusions here are lorazepam, zopiclone, eszopiclone and zaleplon. Further, will prescribers heed the spirit of schedule H1 restrictions? Unfortunately, the schedule provides no disincentives for prescribers in selecting the listed drugs without due care.

The problem of antibiotic resistance runs deep and is multifactorial. In addition to curbing OTC sale, improving microbiology support, continuous surveillance of antimicrobial sensitivity-resistance patterns, implementation of antibiotic policy at all levels of healthcare, continuous awareness generation among medical students regarding rational use of antibiotics and regular prescription audits are some of the other widely recommended measures; all of which are seriously lacking in India. The government has taken a first step by amending the law. There are indications that the Indian Council of Medical Research will commence a nationwide antibiotic surveillance program coupled with capacity building in antibiotic policy making and stewardship. Medical teaching institutions and other hospitals now need to do their bit by implementing the other measures in a concerted and sustained manner.

Monitoring the impact of Schedule H1 is a challenge. This opens up new research possibilities for Indian pharmacologists and pharmacists and other readers of this journal. Such research will not just be good academic exercise but will have major societal relevance.

The schedule H1 drugs were mainly allocated to restrict the selling of antibiotics through over the counter (OTC) sales, after it was noted that any number of these drugs could be bought from pharmacies across India without any limitations.

Irrational prescribing of antibiotics and other drugs by doctors and chemists lacking a registered pharmacist has contributed to the increasing antibiotics resistance and tolerance of psychotropics.(4,5) In response to these serious issues, antibiotic forums, scientific meetings and symposiums were conducted by medical fraternity and various educational institutions.

As a result, the Government of India issued a gazette notification, GSR 588 (E) dated on 30. 08. 2013 regarding schedule H1 Drugs which shows the importance of this schedule.

Schedule H1 Drugs(1,2):

The schedule H1 drug includes 3rd & 4th generation antibiotics, anti-tuberculosis drugs and certain habit-forming drugs like psychotropic drugs.

To dispense these drugs two main criteria have to be followed strictly.

1) The drug supplied under the schedule H1 specification should be recorded in a **separate register at the time of supply, mentioning the name and address of the prescriber, name of the patient, and the name of the drug along with the quantity supplied.** This register has to be maintained confidentially up to three years and should be open for inspection.

2) The schedule H1 drugs should be labeled with the **symbol Rx in red**, clearly displayed on the left top corner of the drug label. The label should also bear the following words in a box with a red border.

"Schedule H1 Drug-Warning(1):

-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."

List of Schedule H1 Drugs

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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. EthambutolHCl
27. Ethionamide
28. Faropenem
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

The schedule H1 drug list, however, shows no limitation of using the drugs as topicals or for external use such as in ophthalmic, ear or nose preparations.(1)

It is a known fact that a gazette notification alone will not help. Apart from this several measures have to be executed by the respective authorities at all levels.

II. CONCLUSION

Surveillance of OTC sales, Studying patterns of antibiotic sensitivity and resistance Launching of appropriate antibiotic and psychotrophic policies in a healthcare facility Creating awareness about rational use of antibiotics in all levels of medical setups including teaching medical institutionsConducting frequent pharmacy inspections

Illegal drug trafficking activities can be eliminated by categorizing drugs as scheduled drugs; this ensures patient health and safety. Ultimately, the registered pharmacists should firmly understand their responsibility in adequately managing drugs being sold through their pharmacy under the drugs regulatory law.

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