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A REVIEW ARTICLE ON SCHEDULED DRUGS IN RETAIL PHARMACY

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ABSTRACT

Background: In the Drug and Cosmetics Rules, the drugs that stated under the Schedule H, Schedule X and Schedule G are needed to be sold by the retail on the prescription of a Registered Medical Practitioner only. Currently Schedule H and Schedule X contain 510 and 15 Drugs, subsequently. The new Schedule H1 has introduced that involves specifically 3rd and 4th generation Antibiotics, specific habit forming drugs and Anti-Tubercular Drugs. The prime objective of Scheduling system is to secure significant access to medicines during balancing public health and safety the schedule drugs which are sold across India are analysed by drug database pharmaTrac. Among 1600 regularly prescribed medicines, barely 656 are presently enclosed under the four Schedules (Schedule H, H1 Schedule X and Schedule G). But only 50% of the pharmacists were aware of schedules. Efforts are taken to reduce opioid related misuse of schedule X. prescribed drug monitoring program (PDMPs) which allows health care providers to access prescription history information to identify patients at risk for addiction. For antibiotics, the patterns of resistance are developed and as a result there classification needs to be re-evaluated on regular basis. In spite of some loopholes, online pharmacy has tremendously increased the sale of schedule drugs. **Conclusion:** It lays a strong foundation for re-evaluating the current drug schedule system. It also fills some of the major gaps in terms of drug classification and its implication. Building further on this work and developing robust process recommendations and technology based suggestions for implementing a more robust drug schedule system in the dynamic and complex Indian healthcare environment is considered.

KEYWORDS: Dispensing, schedules update, drugs and cosmetics act amendments, monitoring drug schedule system, $PDMP_S$.

BACKGROUND

Scheduled drugs comes under Drug and cosmetic Act which has been amended from time to time in the last 15 years, by Mashelkar committee Report[1] and the Ranjit Roy Choudhary Committee Report (2013) and most recently, the Drug and Cosmetics (Amendment) Bill 2015.[1]

The present classification of medicines in schedule G, H, H1, X is outdated, and should be thoroughly refreshed. The prime aim of the scheduling system is to guarantee fitting access while adjusting general public health and security can bring about progress in access of medications without compromising the public wellbeing. The challenges faced because of current scheduled grouping of medications accessible in Indian market and likely mechanisms to re classify every medicine for lucidity and better execution. As of now, an enormous no of medications are not ordered under any of the schedules, prompting to confusion.

MAIN TEXT

We likewise broke down various administrative frameworks including United States Food and Drug Administration, Medicines and Healthcare Product Regulatory Agency in UK, Therapeutic Goods Administration planning framework from Australia, and the World Health Organization, to recognize probably the prescribed procedures being trailed by these agencies.[4-7] The online selling drugs across India is by multiple information sources like 1mg drug database, PharmaTrac.[2]

A brief overview regarding definition of these drug classes and related guidance's given in the table 2.

Out of 1,600 odd drugs listed in D&C Act, many ordinarily recommended medicines have no reasonable prescription direction for all stakeholders including the Registered Medical Practitioners, pharmacists, manufacturers and the regulators.

Many commonly prescribed medications have no clear prescription guidance which is included in table 3.

There are various overlaps as far as medication substances covered under Schedule G, H, H1 and X, prompting execution difficulties and leaving choices open translation. For instance, Antibiotics and habit forming medications are being covered in every one of these schedules.

Schedule H records a wide detail called as anti-infection agents, in spite of numerous normal antibiotics like Amoxicillin, Azithromycin, Amphotericin B and so forth are not covered as discrete details, leaving scope for interpretation.[3] Numerous higher antimicrobials being covered under Schedule H1 yet the rundown in not exhaustive.

Schedule X fundamentally covers habit framing drugs, which have the capability of being mishandled. A portion of the habit forming drugs are as yet covered under Schedule H and H1. For instance, Schedule H contains barbituric acid, phenobarbital, phenothiazine etc. and Schedule H1 contains medications like diazepam, tramadol, midazolam, pentazocineetc. which likewise are habit forming medicines and have misuse potential. Besides, Schedule H makes reference to barbituric acid and phenobarbital, while Schedule X notices barbitals, Amobarbital, Cyclobarbital and so on again leaving space for understanding on arranging specific medications. ScheduleH additionally records a wide detail as Narcotic Drugs recorded in NDPS Act 1945.[3] The vast majority of medications in schedule X are not utilized clinically and is once more outdated.[3] The endorsed guidelines of consistence for schedule H-1 medicines to forestall misuse are inadequate and require parcel of speculation of human asset to direct assessments to check for consistence. Nutraceuticals and vitamin supplements which has to be taken under physician supervision are not differentiated in the present system of scheduled classification Eg: Vitamin A and D leads to hyper-vitaminosis.[10,11]

Schedule G contains a rundown of 50+ medications incorporating a few antihistamines with a name necessity according to Rule 97stating that 'Caution: it is hazardous to take this arrangement besides under medical supervision'.[3] This brings up an issue if these medications can be apportioned without a solution, and if these medications ought to be a piece of both Schedule H and Schedule G, or on the other hand if direction under Schedule G ought to have been changed to give further explanation. The Schedule G is an obsolete timetable with no reasonable direction for the stakeholders.[9]

There ought to be rundown of substances which can be sold without a permit, and this should be obviously separated from OTC medications. Presently this incorporates items, for example, calcium preparations without nutrients, disinfectant moisturizers, medicated mouth washes/rinses, cough and cold preparations without antihistamines or substances included under NDPS Act[12] as per D&C Act those drugs which are not covered under schedule H, H1, X and G and there formulations are considered OTC (On The Counter Drugs). As of now there is no particular rule for skin medications. As per D&C, if the medication substance follows this rule, it will have covered under Schedule H. "The salts, esters, derivatives and preparations containing the above substances barring those intended for skin or external use (with the exception of ophthalmic and ear/nose preparations containing anti-microbial and/or steroids) are likewise covered by Schedule H.[3] Drugs covered under NDPS Act[12] are included in all Schedules H,H1 and X[3] and all drugs acting on central nervous system are not habit forming drugs but only some of the medicines which has a high abuse potential.

According to the D&C Act and Rules there is no checking of medications being prescribed by AYUSH experts but safety and efficacy of these medicines are reviewed and monitored from time to time.

A key challenge identified during this schedule study includes.

In India, the drug store industry is generally divided all through the country; with around 8-8.5 Lac authorized retail drug sale premises. Because of this there is a progression of consistence challenges including.

- Absence of pharmacist, patient counselling and drug information to the patient.
- Sale of medications without prescription, there by prompting illicit drug use.
- Absence of records for sensitive prescriptions like Schedule H1.
- Absence of effective mechanism of review of not of standard or prohibited drugs announced, Sale of medications to the patient without bill might lead to loss of tax collection.

The WHO has delivered a rule that might help supports in deciding the shift from professionally prescribed medicine to OTC. Direction recommends that the item should have the accompanying attributes.[16]

- Sales volume is sufficiently high during the time of showcasing to discover that the item is widely utilized by the customer.
- Item has been made accessible in the past solution status for enough years. This period fluctuates from one country to another.
- Post-market studies on information shows no specific reason for concern and there are no genuine unfavourable occasions that have increment unduly in recurrence during the promoting that is all.

1. Improvement and implementation of an unmistakable rule where any proper portion blend falls under the medication class of a substance with the most elevated class in the mix. For instance, if a proper portion blend incorporates two medication substances inside which one has a place with Class II and another has a place with Class III b, the

naming, solution and administering rules applicable to Class III b ought to be kept.

2. Foster a different medication grouping classification system for skin planning of every medicine, as opposed to characterizing them in a similar class as their oral and parenteral class to further develop access without thinking twice about wellbeing.
3. A notification gave by the Union Ministry of Health and Family Welfare in March 2017 incorporates plans for an electronic stage will be created and kept up with by an independent body under the Ministry of Health and Family Welfare. All wholesalers and merchants will likewise be needed to enlist themselves on the gateway and enter details of stocks got and provided by them to additional merchants or retailers. The pharmacy outlets has to enter details of medicines received ,sold and returned to manufacturer.[13,14]
   Satisfactory admittance to medicines, we suggest the accompanying Pharmacist ought to be needed to transfer just remedies for drugs having a place with Class III b (higher anti-microbial), Class IV a and Class IV b (habit forming) in view of the proposed grouping classification, to restrict interruption to the current system and amplify consistence. Drugstores with various choices to recognize a suitable entryway and coordinate it with existing work process without significant interruption.
4. Central body ought to develop a central server based climate where every one of the transferred prescriptions is shared and checking.

Studies of prescription drug monitoring program (PDMP) impact by domain of opioid-related outcome measure.

$PDMP_S$ are implemented in order to reduce Opioid-related public health burden of schedule drugs.

Some of the critical findings of this implementation are.

- Using PDMPs will tend to increase reporting and also in monitoring of controlled prescriptions, it will reduce the chance of opioid misuse.
- Four domains namely- Opioid prescribing, Opioid diversion and supply, Opioid misuse, and Opioid - related morbidity and mortality are frequently examined in evaluating PDMP impacts.
- The study of association of PDMP implementation and opioid related outcomes do not show any pattern of visible change.
- Use of PDMPs by providers prior to writing a prescription for opioids may be mandatory or optional, and states vary in the responsibilities which arises by any negative outcomes associated with misuse or abuse by their patients.[5]
- PDMPs also vary in the frequency with which they get data from various pharmacies.
- The timeliness and accuracy of PDMP data varies considerably across states, as does the frequency and consistency of use by providers.
  With patient prescription history at their disposal, providers can not only verify the patient's current prescriptions to avoid doctor shopping or drug abuse, but can also avoid potentially dangerous non-controlled drug interaction.
  Studies have reported that many clinicians find PDMPS useful as a communication tool and interaction with patients.[19, 20]
- Rasubula et al[21] found that dentists reducing their prescription of opioid analgesics in a dental urgent care centre care correspondingly increased their use of non-opioid analgesics, such as Acetaminophen.

TABLE LEGEND SECTION

Table 1: Amendments in Drugs and Cosmetics act.

YEAR	Amendments in Drugs and Cosmetics act
2015	Additionof new chapter IIIA.
2017	Sec.3 of Drug & Cosmetic act is amended.
2018	Guidelines for clinical trials of drugs.
2019	Additional requirements of labelling of the act.
2020	Cosmetics rules regarding import of cosmetics.

Table 2: An overview of current Drug Schedule classification.

Drug Schedule	Definition	No. of covered	medicines	Prescription guidance
Schedule G	Schedule G consists for drugs that can be administered only under supervision of a Registered Medical Practitioner (RMP)	57		It is dangerous to take this prescription besides under clinical trial.
Schedule H	Schedule H consists of drugs which are required to be dispensed on prescription of Registered Medical Practitioners (RMP)	537		Medicines to be sold only on prescription of a RMP
Schedule H1	Schedule H1 consists of drugs including antibiotics, habit forming drugs and a few anti TB drugs which were abused under Schedule H, and now have a regulation on its sales and additional warning to the patient	46		Medicines to be sold only on prescription of a RMP; pharmacist to maintain a register/record of all medicines sold

Schedule X	Schedule X consists of drugs which are required to be dispensed on prescription of Registered Medical Practitioners (RMP) It requires special retail license for selling these medicines.	16		Medicines to be sold only on prescription of a RMP prescription copy to be preserved for two years and records of all Medicines

Table III: Examples of Categories & Substances not covered under current Drug Schedules.

DrugCategory	DrugSubstance
Thyroid hormone	Thyroxine
Anti-epileptic drugs	Carbamazepine
DPP-4 inhibitors	Sitagliptin
Theophylline & its derivatives	Doxofylline
	Theophylline
Mucolytics	Acebrophylline
Serotonin antagonists (5-HT3 antagonists)	Ondansetron
Sulfonylureas	Glipizide
Angiotensin receptor blockers(ARB)	Azilsartan
Beta-blocker	Bisoprolol
Calcium channel blockers- Dihydropyridines (DHP)	Cilnidipine
Nootropic agent	Citicoline
Selective Seretonin Reuptake inhibitors (SSRIs)	Dapoxetine
Sodium-glucose co-transporter 2 (SGLT2) inhibitors	Canagliflozin

Analysis of current medicines available in the market inspired a framework for classifying medicines into 5 category given in table4.

Table IV: Recommended Drug Classification System.

Drug Description Prescription Class	Definition	Description	Prescription Guidance
ClassI	Over the counter medicines	Includes medicines that do not require a prescription form a Registered Medical Practitioner(RMP)	Prescription not require
ClassII	Prescriptionmedicines	Includes all prescription medicines and will need to have a valid prescription from a Registered Medical Practitioner (physical or scanned) to be dispensed	Prescription from RMP required (physical or scanned)
Class IIIa	Antibiotics	Includes all the antibiotics and willneed to have a valid prescription from a RMP after following appropriate diagnostic guidelines; digital record of the prescriptionandpatienttobestoredand Archived	Prescription from RMP required (physical or scanned)
Class IIIb	Higher antibiotics	Includesalltheantibioticsbeingusedin severe infections and having a higher risk of developing resistance; required Registered Medical Practitioner to follow appropriate diagnostic guidelines along with mandated culture sensitivity tests to prevent drugresistance	Prescription from RMP required (physical or scanned). Prescription to be uploaded on thee-portal.
Class IVa	Habit forming medicines	Includes all the habit-formingmedicines with a risk of being abused, and hence usage of which need to be tightly regulated	Prescription from RMP required; Prescription to be uploaded on thee-portal.
Class IVb	Habit forming medicines (with high abuse potential)	Includes all the habit-formingmedicines with a very high risk of being abused, ideally overlapping with the drugs included under current NDPS Act; usage to be tightly regulated with additional special license requirement for dispensing thesedrugs	Prescription from RMP required; Prescription to be uploaded on thee-portal.
Class V	Banned	Includes all the medicines that are currently banned in India	Not to be sold

Table-v includes list of medicines changed from prescription medicine to OTC category by USFDA.

Table V: Drug Substances switches from prescription to OTC category by US FDA.

Drug Category	Drug Substance	Year of switch (DD-MM- YYYY)
H1 Antihistaminics (second Generation)	Fexofenadine	24-01-2011
	Levocetirizine	11-01-2017
	Cetirizine	09-11-2007
Corticosteroids	Fluticasone furoate	02-08-2016
	Fluticasone proprionate	23-07-2014
	Adapalene Topical	08-07-2016

Domain 1: Opioid prescribing behaviour.

States/ Years Examined	Outcome measure	Design/Methods	Findings	Evidence for PDMP benefit
New York; 2012-2014	Frequency and volume of opioid prescriptions by dentists in a dental urgent care centre	Cross-sectional survey of a dental urgent care system centre 3 months before and 6 months after implementation of a PDMP.	Total prescribed opioids decreased 78% by dentists in a dental urgent care centre after a mandatory PDMP was implemented.	Yes

Domain 2: Opioid diversion and supply.

Reisman, 2009[12]	**PDMP and non- PDMP states; 1997-2003**	**State prescription opioid shipments**	**Compared state prescription opioid shipments in 14 states with PDMPs (intervention group)and 36 states without PMPs (control group).**	**States with PDMPs received fewer oxycodone shipments that non-PDMP states, opioid shipments in all states continued to rise.**	**Yes**
Surratt,2014[26]	Florida;2009-2012	Quarterly prescription opioid diversion rates	Changes in prescription opioid diversion rates identified using quarterly laws enforcement data after implementation of PDMP	Significant decline in oxycodone diversion.	Yes

CONCLUSION

It lays a strong foundation for re-evaluating the current drug schedule system. It also fills some of the major gaps in terms of drug classification and its implication. Building further on this work and developing robust process recommendations and technology based suggestions for implementing a more robust drug schedule system in the dynamic and complex Indian healthcare environment is considered.

The current study conducts a comprehensive assessment of drug schedule system and its implementation mechanism.

The Study refers to drug classification system of different countries to draw an inspiration how each drug has been classified by different countries. But the Current study does not consider a detailed classification of topical salts of each drugs could be classified, or nutraceutical products which currently do not have a prescription should be classified.

Establishing a conceptual framework for PDMP evaluation is helpful in implementation and it is identified only a single study examining opioid misuse as an outcome of PDMP implementation[15], a concerning gap given the level of national concern about opioid misuse and its potential consequences for leading to abuse. More sophisticated analysis of specific components of PDMPs will be required to fully understand widely varying impacts across states.

Although PDMP implementation has been initiated across the United States, little consistent evidence has yet emerged to demonstrate PDMPs' impact on out- comes of greatest importance, whether more proximal targets such as prescribing behavior or distal out- comes such as opioid misuse, diversion, morbidity and mortality. We offer a call to action to engage in rigorous examination of PDMP impacts across the range of domains identified here, and particularly with regard to opioid misuse, and to do so with a careful eye to understanding features of PDMP legislation and implementation associated with positive outcomes. This call comes at a time when the field of PDMP evaluation is rapidly maturing and more information is becoming available through data sharing and linking with electronic medical records. The increased analytic capacity enabled by such growth should directly facilitate the examination of algorithms for identifying opioid prescribing, misuse, and abuse that are so much a part of the promise of PDMPs, but which have not yet achieved their full potential in mitigating opioid-related harms for individuals and populations.

Despite the fact that PDMP execution has been started across the United States, little predictable proof affects results of most prominent significance.

Abbreviations: PDMP-prescribed drug monitoring program, RMP-Registered Medical Practitioners, OTC-On the Counter Drugs, D & C-Drug & cosmetics, NDPS-the narcotic drugs and psychotropic substances act. USFDA-The united states food and drug administration.

REFERENCES

1. Mashelkar D. A Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs. Ministry of Health & Family Welfare, Government of India, 2003.
2. AIOCD-AWACS, Pharma Trac, 2017.
3. MalikV. Lawrelatingto Drugsand Cosmetics. 25 Edition 2016. Eastern Book Company, Lucknow.
4. United State Food & Drug Administration. Drug Safety and Availability. Available from: https://www.fda.gov/Drugs/DrugSafety/default.htm. [Accessed Aug2017].

5. Therapeutic Goods Administration. Scheduling basics. Available from: https://www.tga.gov.au/scheduling-basics. [Accessed Aug2017].
6. Medicines & Healthcare products Regulatory Agency. Medicines: re classify your product Available from: https://www.gov.uk/guidance/medicines-reclassify-your- product. [Accessed Aug2017].
7. World Health Organization (WHO). Guidelines for Regulatory Assessment of Medicinal Products for Use in Self-Medication (Geneva2000).
8. Ahmad A, Chandra S, Kanth K, Patel I, Parimalakrishnan, Mohanta GP, Balkrishnan R. Changing Pharmaceutical Regulation in India to Promote Rational Use of Antimicrobials. Asian Journal of Biomedical and Pharmaceutical Sciences, 2012; 2(15): 1-5.
9. Suggestion from IPA on drug and cosmetic Rule 1945. The Indian Pharmaceutical Association. Available from: http://www.ipapharma.org/news/Suggestion%20from%20IPA%20on%20Drugs%20&%20Cosmetics%20Rules%201945.pdf.[Accessed Aug 2017].
10. Hyper vitaminosis A. National Health Portal Of India. Available from:https://www.nhp.gov.in/disease/eye-ophthalmology-hypervitaminosis-a.[Accessed Aug 2017].
11. Koutkia P, Chen T, Holick M. Vitamin D Intoxication Associated with an Over-the-Counter Supplement. N Engl J Med, 2001; 345: 66-67.
12. Ministry of Law and Justice. The narcotic drugs and psychotropic substances act, 1985.Available from: http://lawmin.nic.in/ld/P-ACT/1985/The%20Narcotic%20Drugs%20and%20Psychotropi c%20Substances%20Act, %201985.pdf. [Accessed Aug2017].
13. Report of sub-committee constituted by the drugs consultative committee to examine the issue of regulating the sale of drugs over internet under the drugs and cosmetics rules, 1945; 30th September 2016. Available from: http://www.cdsco.nic.in/writereaddata/Sub-Committee%20Report%20on%20e-pharmacy.pdf. [Accessed Aug2017].
14. Public consultation regarding regulation of sale of drugs in the country. Available from: http://www.cdsco.nic.in/writereaddata/public%20notice16marc h.pdf. [Accessed Aug2017]
15. United State Food & Drug Administration. Prescription to Over- the-Counter (OTC)Switch List. Available from:https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm106378.htm. [Accessed Aug2017].
16. World Health Organization (2000). Guidelines for Regulatory Assessment of Medicinal Products for Use in Self-Medication; 2000. Available from: http://apps.who.int/medicinedocs/pdf/s2218e/s2218e.pdf [Accessed Aug2017].
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