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REVIEW ON SCHEDULE H AND H1

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ABSTRACT: From 1 Mar 2014, Schedule H1 has been created and modified by the Drug and Cosmetic Act of 1945. It has been expected for a while but now that it's there, irrational prescription of antibiotics and other drugs by doctors and chemists, force, needs wide publicity and a critical look, from all physicians and healthcare providers in general and the community of pharmacologists and pharmacists. Antibiotic resistance is on the rise, and people are becoming more and more tolerant of psychoactive drugs. Third- and fourth-generation antibiotics, anti-tuberculosis medications, and a few habit-forming pharmaceuticals such as psychotropic drugs are therefore included in Schedule H1 substances. In India, a group of prescription medications known as Schedule H is included as an appendix to the Drugs and Cosmetics Rules, 1945, which were first adopted in 1945. These are medications that require a prescription from a licensed physician in order to be acquired over-the-counter. The Drugs and Cosmetics Act and Rules apply to the production and distribution of all drugs. On the recommendation of the Central Drugs Standard Control Organization [1] at the Ministry of Health and Family Welfare, which is a division of the Drugs Technical Advisory Board, it is occasionally changed. The most recent schedule H (2006) includes 536 medicines, ranging from zuclopenthixol to abacavir. However, Schedule H rules are less strictly enforced in India than Schedule X statutes, which need a stricter documentary trail.

KEYWORDS: Schedule H, Drug and cosmetic Act 1945, Antibiotic, Central Drugs Standard Control Organization,

INTRODUCTION

The schedule H1 notification of the government of India on August 30, 2013 as an amendment to the drug and cosmetics rules of 1945 has now come into force from March 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 required and meticulous storage and dispensing records). The schedule is primarily intended to control the rampant use and include a large component of misuse through over-the-counter dispensing of antibiotics in India. It is open secret that practically any drug is OTC in India and can be produced in small or large quantities if one knows the right retailers and distributors. People who are below the 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 to 3 days for immediate symptoms relief.

What are the immediate implications of the schedule H1 restrictions? Currently, 46 drugs have been placed under this restricted category. Will these restrictions work in dampening rampant OTC sale of antibiotics? Let us hope that awareness, which this legal provision generates, will have a different effect in itself. To do this would mean more elaborate and time-consuming cross-checking of the inventory. Antibiotic resistance is a complicated and multifaceted issue. Along with reducing OTC sales and enhancing microbiological support, continual monitoring of antimicrobial sensitivity-resistance patterns, implementation of antibiotic policies at all levels of healthcare, ongoing education of medical students regarding appropriate use of antibiotics, and regular prescription audits are some other highly advised measures that are all woefully underutilized in India.

By changing the law, the administration has already made a first step. Now, medical schools and other hospitals must contribute by putting the other steps into practice in a coordinated manner and persistent manner. It is difficult to track Schedule H1's effects. This creates fresh study opportunities for Indian pharmacologists, pharmacists, and other journal readers. Such research will not only be an excellent academic exercise but will also be highly relevant to society. After it was discovered that any number of these medications could be purchased from pharmacies across India without any restrictions, the schedule H1 pharmaceuticals were primarily assigned to restrict the sale of antibiotics through over-the-counter (OTC) sales. Antibiotic resistance has increased as a result of doctors and pharmacists without a trained pharmacist irrationally prescribing antibiotics and other medications.

In India in the last five years, the consumption of antibiotics has climbed by 6% to 7% annually (from 2005 to 2009). 2, 4 Between 24 and 67% of people in India use antimicrobial agents. 3 A research by Akram Ahmad et al. (2012) at a community-based hospital in south India revealed that 51% of antibiotic prescriptions were unnecessary. 3 These findings offer strong support for the argument that antimicrobial drugs must be used more judiciously in India. 2, 3, 4 with occurrence of superbug The Indian government was startled and under pressure from several quarters to implement strong regulations for the prudent use of antibiotics. The need for schedule H1 was therefore brought to light, despite the fact that schedule H and schedule H1 are very similar in most respects with only slight change.

THE SUPER BUG

With the discovery of the New Delhi super bug, it became urgent to create a national drug policy for the prescribing of antibiotics. A novel bacteria known as New Delhi metallo-beta-lactamase-1 was identified in India, according to an article in the Lancet in August 2010. (ndm-1). Due to this enzyme, bacteria become resistant to practically all antibiotics, even last-line carbapenems. Although this was discovered in a Swedish patient who had surgery in New Delhi, India is still held responsible because further research has revealed the existence of the same sort of bacterium in residents of New Delhi. 5 In addition to strict infection control in hospitals, community hygiene is also required to prevent the emergence of Literature.

SCHEDULE H1

The schedule H1 drugs were mainly allocated to restrict the selling of antibiotics through over the counter sale As the result the government of India issued a gazette notification GSR 588(E) dated on 30.8.2013 regarding schedule H1 drugs which shows the importance of this schedule. The schedule H1 drugs include 3rd and 4th generation antibiotics, antituberculosis drugs and certain habits forming drugs like psychotropic drugs .The drug supply under the schedule H1 specifications should be recorded in a separate register at time of supply mentioning the name and the 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 confidential up to three years and should be open for inspection. Schedule H1 drugs should be labelled with the symbol Rx in Red display in left top corner of the drug label .The label should also bear the following words in a box with a red border. To combat the irrational drug use that has led to this situation, the Ministry of Health is considering drafting law amendments to include many antibiotics and sedatives, as well as some other drugs, on the schedule h1 list. 7 A provision for spot suspensions/cancellation of The sale licence for violation of The provision of Schedule h1. 13 The proposed rule is in the final stages of drafting and amending the existing Drugs and Cosmetics Act 1945, and it will be officially implemented soon by the ministry. 13 Before the amendment is passed in either house of parliament, the law ministry will examine its viability and may provide suggestions and nods, according to a ministry of health official.

46 drugs comes under the schedule H1 and they are as follows.

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. Cefibuten
16. Cefizoxime
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



are only a few of the medications available. However, there is no restriction on utilising the medications as topicals or for external use, such as in ophthalmic, ear, or nose preparations, on the schedule H1 medicine list. It will be recognised that a gazette notified by itself is insufficient. In addition to this, certain actions must be taken by the relevant authorities at all levels.

46 drugs under strict prescription norm

Recognizing drug resistance as a significant health risk, the Indian government has added 46 medications and their formulations to a brand-new category dubbed "schedule H1." Beginning on March 1, a pharmacist may only dispense any medications listed in this schedule with a registered physician's prescription as described by the Drugs and Cosmetics Act. The shop must keep a separate record of each sale of these medications for at least two years in a separate register.

Strong antibiotics (such as anti-tuberculosis medications), habit-forming painkillers like tramadol, and sleep-inducing anti-anxiety medications make up the majority of these medications. On August 30 of last year, the medications and cosmetics legislation of 1940 was amended by a notification issued by the ministry of health and family welfare.

A.V. Giri, joint commissioner for medicines at the Food and Drug Administration (FDA), told. According to a directive from the central drugs standard control organisation (cdsco), the notification would be put into effect across all of India beginning on March 1, 2014. The enforcement body would be Cdsco. If a violation occurs, the license may be revoked, suspended, or even subject to legal action. Any retail pharmacy may be subject to a surprise inspection by FDA or state drug inspectors, who can also check the register. Schedule H1 medication packaging and their formulations must prominently display the Rx sign in red in the left-top corner of the label. They must also have a red bordered warning on them. A copy of the prescription will be kept by the pharmacist or druggist.

MEANING OF THE NEW SCHEDULE H1 NORM

FOR RETAILERS

Retailers will take longer and put more labour into recordkeeping, which will slow down the dispensing process and will have the patient's address so they can recall medications if there are issues with a specific batch or fake medication. A reduction in over-the-counter (OTC) sales.

FOR DOCTORS

It will assist to reduce resistance in patients if these medications are prescribed with utmost caution. Patients with chronic conditions will visit for follow-up medications.

FOR PATIENTS

Patients who cannot visit doctors frequently but must take specific medications for the rest of their lives may have to pay more for doctor appointments. Patients who cannot buy medicine over-the-counter (OTC) in case of emergency.

SCHEDULE H

Schedule H is a class of prescription drugs in India appearing as an appendix to the Drugs and Cosmetics Rules, 1945 introduced in 1945. These are drugs which cannot be purchased over the counter without the prescription of a qualified doctor. The schedule H consists of 536 drugs which required dispensing on prescription of a registered medical practitioner. The third and fourth generation antibiotics will remain untouched by effective implementation of national policy for containment of antimicrobial resistance which discusses new policy and prevents these antibiotics from being misused in schedule H.

In India, in the last five years, the consumption of antibiotics has climbed by 6% to 7% annually (from 2005 to 2009). Between 24 and 67% of people in India use antimicrobial agents. A research by Akram Ahmad et al. (2012) at a community-based hospital in south India revealed that 51% of antibiotic prescriptions were unnecessary. These findings offer strong support for the argument that antimicrobial drugs must be used more judiciously in India.

With the occurrence of superbugs, the Indian government was started and under pressure from several quarters to implement strong regulations for the prudent use of antibiotics. The need for schedule H1 was therefore brought to light, despite the fact that schedule H and schedule H1 are very similar in most respects with only slight changes.

HOPE OR HYPE

The schedule contains a list of drugs that can be sold only against the prescription of a registered medical practitioner. Only the required amount of medication mentioned in the prescription can be dispensed. These drugs can be supplied only to the licensed parties. The drug label must exhibit the text "Rx" and schedule H drug warning to be sold by retail on the prescription of a registered medical practitioner only. As per the notification March 16, 2006 released by the department of the health under the ministry of Health and Family Welfare.

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.

WARNING

To be sold over the counter only with a qualified physician's prescription.

If it contains a substance listed in schedule h and falls under the narcotic drugs & psychotropic substances act of 1985, it must be marked with the nrx symbol, which must be prominently displayed in red on the left top corner of the label, as well as the words "scheduled h drug."

There will be the following limitations.

These medications will be sold by pharmacists only upon presentation of a prescription and will come in packaging with an obligatory warning printed on it in a box with a red border on the label. The pharmacy will keep a copy of the prescription and keep a separate register for these 46 medications in which the patient's identity and the information about the physician who prescribed the medications will be recorded. Three years must pass before this registry can be destroyed. The order is under the control of the Central Drugs Standard Control Organization (CDSCO). State Drug Inspectors may perform unexpected inspections at pharmacies and chemist shops to check the registers and sale of these 46 medications as a result of violating this rule.

NEED OF WORK

Taking strong view of the fact that antimicrobial resistance (AMR) is increasingly becoming a serious threats to public health, the union health ministry has outline an action plan towards strong implementation of the provisions of the Drugs and Cosmetics (D&C) Rules 1945 to ensure that no drugs including antibiotics in schedule H and H1 category are sold at retail pharmacies without prescription of a registered medical practitioner. Improve the fundamental knowledge advance research to improve the diagnosis H and H1 drugs. Accelerate research to improve treatment for all form of schedule H and H1 in all population and age group. Develop tools and resources to advance research

FUTURE SCOPE

- The proposed schedule H1 is intended to forbid their sale without a prescription from a doctor.
- A new list of medications with stronger antibacterial protection to cut down on free sales or availability.
- The addition of this new schedule H1 would enhance the usage of antibiotics and lessen or postpone the emergence of resistance.

DRAW BACKS

There are certain backdrops that are to be addressed before going to evaluate the advantage and disadvantage of the proposed schedule H and H1 .

The schedule didn't provide any exemption for remote area where access to hospital is not possible.

The guidelines for prescribing and refilling process are not specified.

Inspectors or officials who are going to audit the hospital and pharmacies are not clearly mentioned.

Before evaluating the benefits and drawbacks of the proposed schedule, certain background issues must be addressed.

The contribution of ophthalmic and ENT preparations of drugs specified in the schedule to resistance is almost negligible. As a result, there is no reason to limit the use of these types of formulations. The guidelines for prescribing the drugs listed in the schedule are not clearly stated.

Lifesaving antibiotics may no longer be available as OTC products, resulting in deaths in emergencies.

Many key factors that contribute to resistance are overlooked, such as improper law enforcement and patient compliance issues.

The schedule made no exceptions for remote areas where access to hospitals is impossible.

The prescription and refilling procedures are outlined below.

SUGGESTIONS

Storage of duplicate prescription for every dispensing of stated drugs for a limited period and mandate number of inspection may increase the vigilance.

Standard treatment guidelines are to be revised and there is a need to come up with an official stage with subsequent wide distribution among the rmps.

Along with implementation of new regulations old ones are to be revised .

Educational campaigns will be conducted among the general public as well as health care teams in order to raise awareness and gain their support.

Along with the implementation of new regulations, existing ones will be revised.

Proper prescription guidelines regarding when to prescribe certain classes of drugs are to be provided, with some general guidelines developed by the health ministry.

Increasing public awareness of this issue through campaigns; some exceptions will be made for remote areas with limited access to health care.

As there is a risk of contamination, proper packaging and labelling requirements must be specified.

REGULATIONS FOR DRUG SALES UNDER SCHEDULE H1:

Drugs included in Schedules H and X must only be sold by retail on a Registered Medical Practitioner's prescription, according to the Drugs & Cosmetics Rules. Right now, there are 510 pharmaceuticals on Schedule H and 15 drugs on Schedule X, respectively. Through Gazette notification GSR 588 (E) dated 30-08-2013, a new Schedule H1 containing specific third and fourth generation antibiotics, certain habit-forming medications, and anti-TB pharmaceuticals was recently established. The following conditions must be met for certain medications to be sold in the nation:

1. medicine listed in Schedule H1 is supplied, the name and address of the prescriber, the patient's name, the drug's name, and the quantity supplied must be documented in a separate register. These records must be kept for three years and be available for examination.

2. The drug included in Schedule H1 must be labelled with the following information in a box with a red border, together with the symbol Rx, which must be prominently displayed in red on the left top corner of the label.

Several of the negative effects of several medications on schedules H and H1

These side effects may go away if your body becomes used to the medication while you're receiving therapy. Your healthcare provider might also be able to provide you with information on how to lessen or avoid some of these adverse effects. Consult your doctor if any of the following side effects persist, are bothersome, or if you have any questions about them.

- ☐ cramping
- ☐ decreased interest in sexual intercourse
- ☐ difficulty having a bowel movement(stool)
- ☐ feeling of constant movement of self or surrounding saaa
- ☐ hair loss or thinning of The hair
- ☐ inability to have or keep anerection
- ☐ increased sensitivity of The skin tosunlight
- ☐ loss in sexual ability, desire, drive, orperformance
- ☐ musclespasm
- ☐ pinpoint red or purple spots on Theskin
- ☐ redness or The discoloration of Theskin
- ☐ restlessness
- ☐ sensation ofspinning
- ☐ severesunbur
- ☐ abdominal or stomach pain
- ☐ back, leg, or stomach pains
- ☐ black, tarry stools
- ☐ bleeding gums
- ☐ blistering, peeling, or loosening of The skin
- ☐ bloating
- ☐ blood in The urine orstools
- ☐ blood yurine
- ☐ blue lips and fingernails
- ☐ blur red vision
- ☐ burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- ☐ chestpain
- ☐ chills
- ☐ clay-colored stools
- ☐ cloud yurine
- ☐ cold sweats
- ☐ confusion
- ☐ constipation
- ☐ cough or hoar seness
- ☐ coughing that sometimes produces a pink frothysputum
- ☐ cracks in The skin
- ☐ dark enedurine
- ☐ decrease in urine output or decrease in urine-concentratingability
- ☐ decreased frequency or amount ofurine
- ☐ diarrhea
- ☐ difficult, fast, or noisy breathing, sometimes withwheezing
- ☐ difficulty with breathing
- ☐ difficulty with swallowing
- ☐ dizziness, faintness, or light headedness when getting up from a lying or sitting posit

The following restrictions will be applicable.

The packaging of these drugs will have mandatory warning printed on them in a box with a red border on the label and will be sold by chemists on production of a prescription. The chemist will retain a copy of the prescription and maintain a separate register for these 46 drugs where the name of the patient and the details of the doctor who prescribed the drugs will be noted. This register will have to be kept for three years before being destroyed. The Central Drugs Standard Control Organisation (CDSCO) has the responsibility to

the order. Violation of this provision can result in State Drug Inspectors can conduct surprise inspections at the pharmacies and chemist shops to check the registers and sale of these 46 drugs under Schedule H1.

RECENT DEVELOPMENTS:

India's medical societies came together for the first time to organise a magnificent conference. On August 24, 2012, a Roadmap to Tackle the Challenges of Antibiotic Resistance was held in Chennai to explore the issue of antimicrobial resistance and potential remedies that may be used in India. Additionally, international experts were asked to discuss the efforts high-income nations are making to combat antibiotic resistance.

To help with the creation of the road map, it was intended to garner a wide spectrum of views and viewpoints. The "Chennai Declaration" was the result of this summit. One of the greatest medical advancements has been the development of microbes, which has helped India's rate of morbidity and mortality from infectious diseases decline. However, irrational antibiotic use results in resistance and lengthy hospital stays.

The New Delhi metallo-beta-lactamase-1 (NDM-1) was found in India in August 2010, according to a report in Lancet. This enzyme renders bacteria resistant to all antibiotics, including carbapenems. [3] In response, the Indian government established a task committee for the evaluation and formulation of antibiotic resistance prevention measures. The Government of India is enacting strict regulations for the prudent use of antibiotics in the form of a new addendum to the D and C Act of 1940. The Indian government has not yet

introduced this schedule, known as "Schedule H1," and more information is still needed. In 2013, a formal introduction of the final text of the proposed rule and change to the D and C Act 1940 will take place.

The revised schedule has some drawbacks because it includes antibiotics that are used in ophthalmic and ENT preparations but have low levels of resistance. Many antibiotics are only accessible in tertiary care hospitals; they are not available in outlying or rural areas. The planned schedule makes no mention of how to get a prescription filled again. Since many essential antibiotics may no longer be sold over-the-counter, health care practitioners must develop plans to ensure patient compliance and access to these medications.

A set of official Standard Treatment Guidelines (STGs) should be developed by the STGs committee for distribution to registered medical professionals (RMPs), and educational campaigns should be run among the general public and the medical community to raise awareness of the implementation of new regulations. also need to be mentioned. randomly examining.

Along with improper dispensing, the government must prioritise the implementation of laws that offer screening facilities for accurate infection diagnosis, close legal loopholes that permit non-pharmacist employees to open and work in pharmacies, prevent self-medication, and raise awareness of the proper usage of antibiotics among the general public and medical professionals. The planned timeline must be modified to include the development of policies and their passage into legislation.

Antibiotic prescription best practises, exceptions for rural places with limited access to healthcare, and standards for proper packaging and labelling.

RESULT AND DISCUSSION:

Challenges identified with current Drug Schedule H1 and h1 drug system:

- Current drug classification system primarily focuses on two drug classes including Schedule H, H1
- A brief overview regarding definition of these drug classes and related regulatory guidance is provided in the Table.

Drug Schedule	Definition	No. of Medicines Covered ¹	Prescription Guidance
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

There are several drug compounds that are covered under Schedule H, H1 drugs, which creates implementation issues and leaves choices open to interpretation. Antibiotics and drugs that promote drug addiction, for instance, are covered in each of these schedules. Despite the fact that many popular antibiotics, such as Amoxicillin, Azithromycin, and Amphotericin B, are not covered as separate line items, Schedule H provides a broad line item (no-32) titled "Antibiotics," giving room for interpretation. Schedule H1 covers a number of stronger antibiotics, however the list is not exhaustive.

Some addictive substances are still protected by Schedules H and H1, nevertheless. For instance, Schedule H has pharmaceuticals like barbituric acid, phenobarbital, phenothiazine, etc., while Schedule H1 contains similarly habit-forming medications like diazepam, tramadol, midazolam, pentazocine, etc.

SUMMARY

We believe that the current study lays down a strong foundation for revaluating the current drug schedule system and filling some of the major lacunae in term of drug classification and its implication.

We would consider building further on this work and developing robust process recommendation and technology based suggestion for implementing a more robust drug schedule system in the dynamic and complex Indian healthcare environment.

CONCLUSION

Along with inappropriate dispensing government has to focus on some more important issues which include: Lack of screening facilities for proper diagnosis of infections. Lack of proper implementation of laws. . Loop holes in existing laws like allowing non pharmacist personnel to have partnership in establishing a pharmacy. . Self medication issues. . Lack of knowledge in public and health care team Before implementing the laws which are throwing the public health into risk government has to remember that "Rome is not built in a day" similarly, forcing to implement laws is not the solution for the issue which is due to many reasons. So, government has to focus on the reasons that led to this situation and then frame laws accordingly.

Even though it is a good move, in the present context it is not possible to implement the new schedule as such. This is to be solved making adequate changes to the proposed schedule and then come up with a modified one that is accepted by all. So, there is a need for the government to consider these recommendations and make required changes in the proposed schedule.

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