

## Schedule H1: Is it a Solution to Curbing Antimicrobial Misuse in India?

Sir,

Antimicrobials are one of the greatest medical discoveries, which have reduced the morbidity and mortality caused by infectious diseases in India. However, the irrational use of antibiotics leads to resistance, prolonged hospital stays, increased risk of adverse effects, and cost of treatment.<sup>[1,2]</sup>

In August 2010, Lancet reported the discovery of a new enzyme in India: The New Delhi metallo-beta-lactamase-1 (NDM-1), which makes the bacteria resistant to all antibiotics including carbapenems.<sup>[3]</sup> In response, the Indian Government formed a task force for assessment and formulation of preventive measures against antibiotic resistance. Strict laws for rational use of antibiotics are being enacted upon by the Government of India in the form of a new addendum to the existing D and C Act of 1940. This schedule known as the "Schedule H1" is yet to be introduced by the Indian Government and is currently awaiting further clarification. The final draft of the proposed rule and amendment of existing D and C Act 1940 will officially be introduced in 2013.<sup>[4]</sup>

The CDSCO is formulating the new schedule and has recommended amending the D and C Act of 1940 to prohibit the over the counter (OTC) sale of 81 antibiotics, cultures and antibiotic sensitivity assays for suspected infections. These rules announced in March 2012, provided technical and regulatory operating procedures to clinicians for diagnosing and treating any infection. It mandated a red color Rx label warning to those 81 antibiotics, which exempted the pharmacies from selling them without a physician's

prescription. Violation of the above recommendation may lead to spot suspensions or cancellation of the licensure to practice for the guilty party.<sup>[4]</sup>

The new schedule is not without shortcomings, since it includes antibiotics used in ophthalmic and ENT preparations, which have negligible resistance. Many antibiotics are available only in the tertiary care hospitals, but not in remote or rural areas. The proposed schedule does not discuss about the process of refilling the prescription. Since, many lifesaving antibiotics may no longer be available as OTC products, health-care professionals have to formulate strategies to maintain their access and patient compliance.

Standard Treatment Guidelines (STGs) committee should come up with a set of official STGs for distribution among the registered medical practitioners (RMPs) and educational campaigns should be conducted among the public and health-care teams to create awareness about the implementation of new regulations. Proper prescription guidelines about utilization of antibiotics, exemptions for remote areas where health-care access is poor, proper packaging and labeling requirements should also be specified. Random checks of pharmacists dispensing the antibiotics and RMPs providing patients with physician samples prohibited for resale can reduce the misuse of drugs. Antibiotic stocks should be audited as black market value for antibiotics might rise, especially for antifungals, antiprotozoals etc., Frequent inspections should be conducted and accordingly reports should be submitted to the respective departments to ensure appropriate use of antibiotics. Sale of newer antibiotics should be allowed in other health-care settings after training the health professionals in rational use of antibiotics.<sup>[5]</sup> Government should make mandatory prescription audit in each hospital by the Pharm.D and M.Pharm (pharmacy practice) graduates, which will generate employment for them as well provide an easy solution to curb misuse of antibiotics.

Along with inappropriate dispensing, government has to focus on implementation of laws that provide screening facilities for proper diagnosis of infections, prevent loop holes in existing laws that allow non-pharmacist personnel into establishing and working in pharmacies, prevent self-medication and promote awareness about appropriate usage of antibiotics among the public and health-care personnel. There is a need for framing policies and implementing them as laws as part of the modifications made to the proposed schedule.

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