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Medical Fraternity Raises Eyebrows over the Quality of Non-Branded Drug

Although the government resolution (GR), which stated that doctors should only prescribe generic medicines to patients, has been put on hold, the medical fraternity has raised concerns over the diktat while raising questions over the quality of non branded drugs. After the National Medical Commission (NMC) came under heavy fire from several associations of medicos, the August 2 GR has been kept in abeyance.

However, the move hasn't pacified the doctors at large as several of their groups are holding meetings with Union Health Minister Mansukh Mandaviya and raising questions over quality of generic medicines. In a letter sent to the Centre, the Indian Medical Association said that less than 1% of generic drugs produced in India are tested for quality. Moreover, a government panel has underlined the problems in the drug regulatory system and attributed them to weak infrastructure, inadequate testing and drug inspection staff shortages. "Before making such regulations, the NMC should take the opinion of doctors, who are crucial stakeholders in the country's healthcare policies.

The commission should adopt a gradual approach to policy changes over time," said a senior doctor. Dr Parthiv Sanghvi, a city-based consultant surgeon, dubbed the NMC as a

"bureaucratically managed doctors (association)". Under the garb of affordable healthcare for all and to decrease medical expenses for the general public, the NMC came out with a 'fatwa' for doctors to prescribe generic medicines. "Has the government forgotten that the World Health Organisation has blacklisted some of the pharmaceutical companies for manufacturing spurious medicines which claimed the lives of many children. The Indian pharmacy was dragged into an international dispute due to such deaths arising from wrong combination generic cough syrups, which were exported by an unregulated pharma company in north India to Gambia.

The government easily puts the onus on doctors but what about the unregulated pharma companies," he said. A senior doctor said there are several reasons due to which the GR received a backlash from the medical fraternity as most of the doctor conferences are sponsored by pharmaceutical companies.

If the new GR is implemented, it will have a big impact on these firms, the medico added. Averting that the rule has the potential to break the nexus between doctors and pharma companies, he said, "Generic names in prescriptions will mean that doctors cannot push the products of any particular company. If that happens, would companies be as willing to sponsor doctors? Maybe not."



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*Indian J Public Health. 2015;59(1):58-60. doi:10.4103/0019-557X.152867 *ARV : Anti-Rabies Vaccine



Possession of E-Cigarettes Violation of Law: Health Ministry (PTI)

Possession of e-cigarettes and similar devices in any form, quantity or manner is in violation of the Prohibition of Electronic Cigarette Act (PECA) 2019, the Union Health Ministry said in a clarification. The clarification was sent to the Ministry of Civil Aviation (MCA) last month, official sources said, adding it will strengthen the enforcement of the ban. The ministry said that though there is no explicit mention of prohibition of individual use of e-cigarette in PECA, the law has been enacted to prohibit the production, manufacture, import, export, transport, sale, distribution, storage and advertisement of e-cigarettes.

“Therefore, possession of e-cigarette within the country in any quantity is not possible without contravening the provisions of PECA, 2019,” said Dr Pulkesh Kumar, Deputy Secretary, Ministry of Health. The ban includes a prohibition on all forms of Electronic Nicotine Delivery Systems, Heat Not Burn Products, e-Hookah and similar devices. The law was enacted in the interest of public health and to protect the people from harm, the health ministry said. Despite heavy penalties and imprisonment, e-cigarettes are reported to be widely available across a range of sources including tobacco vendors, general stores, and online providers.

The health ministry has also launched an online portal to facilitate reporting of violations under PECA. This portal will allow the ministry to take necessary action on violations. Anyone can

report these violations at “<http://www.violation-reporting.in>”. The government has also expressed concern regarding the alarming rise in its use amongst youth. In May, the ministry issued a public notice for effective implementation of the Act. Later in July, the ministry sent notices to 15 websites selling e-cigarettes, asking them to stop advertisement and sale of such products. The ministry, earlier in February, had written to all states and UTs to ensure effective compliance of the government's ban on e-cigarettes. In a letter addressed to chief secretaries of all states and Union territories, it had flagged the sale of ecigarettes at stationary stores near educational institutions.

Draft Notification to Include Antiviral Drugs Oseltamivir & Zanamivir in Schedule H1

The Union health ministry has issued a draft notification to include antiviral drugs oseltamivir and zanamivir into the Schedule H1 of the Drug Rules, 1945, allowing the retailers to store and sell the drug against prescription by maintaining a separate record for the details of the particular sales. These drugs were removed from the Schedule X in the Rules, in 2017 with an intention to add them to the Schedule H1, which was introduced in the year 2013. In a draft notification issued on September 25, the Ministry said that the amendment, which shall come into force on the date of their final publication in the Official Gazette unless otherwise specified, proposes to include oseltamivir as the serial number 49 and zanamivir as 50 in the list of Schedule H1 drugs.



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The draft rules shall be taken into consideration on or after 30 days from the date of the draft notification made available to the public and the ministry said that objections and suggestions received within the period will be considered by the Central government. Schedule H1 was introduced by the government through a notification on August 30, 2013, which contains certain 3rd and 4th generation antibiotics, certain habit forming drugs and anti-TB drugs. These drugs are required to be sold in the country with certain conditions including that the supply of a drug specified in Schedule 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. Such records shall be maintained for three years and be open for inspection.

The drug specified in Schedule H1 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 be labelled with the warning that it is dangerous to take the preparation except in accordance with the medical advice and it should be sold by retail without the prescription of a registered medical practitioner. The health ministry's gazette notification issued on September 15, 2009 had imposed restrictions on the manufacturing and sale of these drugs so that it should follow the conditions as specified for Schedule X of the Drugs and Cosmetics Rules, 1945. It added that it requires permission from the Central Government each time for the export of these drugs. In a notice on June 22, 2017, the then Drug Controller General (India) Dr G N Singh

informed that in February, 2017, the government through a gazette notification withdrew oseltamivir and zanamivir from the list of Schedule X drugs and permitted for sale as similar to drugs under Schedule H1.

The notification was issued following the recommendation of the Drugs Technical Advisory Board (DTAB) in a meeting held on November, 2016, that both the drugs should be included in Schedule H1 subject to the condition that details of the manufacture and sale of the drugs should be submitted by the manufactures to the DCG(I) at regular interval and the DCGI should direct his enforcement officials to keep strong vigil on manufacture, sale of these drugs. Infact, the DTAB has considered the proposal to include these two drugs under the Schedule H in February 2015 itself, observing that oseltamivir phosphate and zanamivir belonging to Schedule X had impacted the sale of the drug in the country, in the wake of a rise in the incidence of swine flu and large numbers of deaths reported during the time.

The Board during then observed that there is an urgent need for oseltamivir formulations to be made freely available putting an end to the toll caused by the ailment and an indigenous H1N1 vaccine has been developed in the country and permitted to be sold without such restrictions. "The above restrictions were imposed in 2009 when it was felt that oseltamivir is the only drug available for treatment of H1N1 virus influenza in humans and it is not desirable to allow indiscriminate and unregulated access to this drug as inappropriate use would lead to the H1N1 virus developing resistance to the drug,

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thereby rendering it ineffective," it said, adding that in view of the situation prevailed in 2015 the notification may be rescinded and fresh notification for the sale of the drug as Schedule H1 drug may be issued which would make increased availability of the drug in the country.

The Board, during the time said that its members were of the view that the drug has been in use in many countries and there are no reports of resistance being developed with the use of the drug. It also recommended that the 2009 notification may be withdrawn and Schedule H1 may be amended to allow sale of the drugs applying the relevant conditions. The Drugs Consultative Committee (DCC), in a meeting in July, 2020, recommended revoking of the notification issued on February, 2017 which mandated permission from the Central Government to be given each time for the export of these drugs, and recommended that the drugs should be notified under Schedule H1. Following this, the drug regulator decided to remove the export restrictions on oseltamivir and zanamivir. It may be noted oseltamivir is sold by Swiss pharma major Roche under the brand name Tamiflu and by various Indian manufacturers under different brand names, while zanamivir has been sold by GlaxoSmithKline under the brand name Relenza, and by various Indian manufacturers under different brand names.

Eye Medicine Sales Grow 5 Times Faster Than Other Drugs

The 'pink eye' outbreak has led to a surge in sales

of ophthalmology medicine. Sales jumped nearly 30% year-on year for the second month in a row in August — outgrowing the overall market by almost five times. The rise reflects the massive incidence of conjunctivitis and eye-complications in the last few months across the country. Overall, sales growth was muted at 6% in the domestic pharma market, estimated at Rs 18,700 crore during the month. The pharma market has slowed from June — hovering around 5-6% growth — pulled down by poor sales of acute therapies, data from market research firm IQVIA showed. Acute therapies including respiratory and anti-infectives grew 4%, as against chronic medicines (used for lifestyle ailments), which posted a 9% growth. Others like cardiac and gastro medicines registered the highest growth amongst large therapies.

Industry experts pointed out that though the data showed ophthalmology and otology (ear medication) clubbed together, the jump is primarily due to eye medicine sales. Within ophthalmology, methyl cellulose registered the highest sales of Rs 51 crore with 13% growth, while the highest growth of 95% was observed in Moxifloxacin. Typically, Moxifloxacin is an antibiotic prescribed for bacterial eye and ear infections, industry experts told TOI. During the month, Sun Pharma maintained top position with a share of 8% in the organised pharma retail market. Others like Macleods, Aristo and FDC improved by two ranks to reach seventh, 10th & 22nd position, respectively. Amongst brands, popular antibiotic Augmentin topped the list with Rs 76-crore sales, followed by antidiabetic Mixtard and antibiotic Monocef.

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Augmentin stood at the top position though sales declined 5%, while among top 10 brands, the highest growth (38%) was observed by Liv-52 with a gain of two ranks to secure the sixth slot. Monocef recorded a growth of 19% while Pan, Thyronorm and Foracort also mopped a robust double digit growth during August. Further, other movers included anti-diabetic Lantus which moved up four ranks to secure the 16th position, pain-relief drug Calpol gained six ranks to secure the 12th position. Monocef and Azithral gained 12 ranks to secure third and 21st positions. The pharma market, which is valued over Rs 2 lakh crore, registered a growth of 10% for the 12-month period ended August.

Strengthening Antimicrobial Resistance Surveillance Systems

Antimicrobial resistance (AMR) has been declared a global public health threat that has the potential to jeopardise the foundations of modern medicine and infectious diseases control [1]. Current estimates suggest that AMR is responsible for approximately 700,000 human mortalities per year [2] with the potential for up to 10 million deaths per year by 2050 if effective strategies to reduce resistance are not implemented [2]. Whilst immediate repercussions to human health have been widely recognised as impetus for action [3], the significance of AMR extends to animal and environmental health sectors [4]. The breadth of the issue, thus, necessitates a collaborative approach to address the multi-faceted AMR crisis [5]. The World Health Organization's (WHO) Global Action Plan (GAP) on AMR was

developed to engage the international community in efforts to address the emerging public health crisis [1]. The GAP describes 5 objectives including: (i) improving awareness on AMR through training, education, and communication, (ii) strengthening knowledge and evidence base through surveillance and research, (iii) reducing the incidence of infection through sanitation, hygiene, and infection prevention measures, (iv) optimisation of antimicrobial medicines in human and animal health, and (v) developing an economic case for sustainable investment for new medicines, diagnostic tools, vaccines, and interventions [1]. The basis for these objectives is to facilitate effective policy and stewardship processes to ultimately produce discernible mitigation efforts against AMR [1].

The second objective of the GAP foregrounds surveillance as an integral component to ascertain the status of AMR in various contexts and monitor progress towards control objectives [1]. The role of continuous AMR surveillance facilitates evaluation of AMR stewardship programmes, interventions, and policy efficacy via the generation of evidence [6]. Moreover, the borderless nature of AMR has emphasised the need for continuous global monitoring [7]. International initiatives such as the Global Antimicrobial Resistance and Use Surveillance System (GLASS) have aimed to provide guidance in assembling and standardising data from national AMR surveillance systems to inform future actions [8]. Whilst surveillance has been outlined as a global necessity [7], the current state of surveillance systems vary greatly across national contexts [9], with some having



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highly structured and effective systems [10] and others with no system or a system under development [8]. The wide variation in the structure and effectiveness of national surveillance systems and the absence of foundational work to facilitate improvement calls for research to better understand the barriers and enablers of national AMR surveillance systems. The aim of this scoping review is to identify and thematically map published literature describing the implementation or evaluation of national AMR surveillance systems.

The objectives of the scoping review are to (1) identify the main thematic categories that are relevant in implementing, utilising, and improving surveillance systems (2) examine reported challenges and successes in utilising surveillance systems, and (3) identify gaps within literature that can be used to design further studies on AMR surveillance systems. PubMed, Web of Science, SCOPUS, and EMBASE databases were searched systematically to identify literature pertaining to implementation, monitoring, and evaluation of AMR surveillance systems. A thematic analysis was conducted where themes within the literature were inductively grouped based on the described content. Results The systematic search yielded 639 journal articles for screening. Following deduplication and screening, 46 articles were determined to be appropriate for inclusion. Generally, most studies focused on human AMR surveillance (n = 38, 82.6%). Regionally, there was equal focus on low- and middle-income countries (n = 7, 15.2%) and trans-national contexts (n = 7, 14.5%). All

included articles (n = 46, 100.0%) discussed barriers to either implementing or utilising AMR surveillance systems. From the scoping review, 6 themes emerged: capacity for surveillance, data infrastructure, policy, representativeness, stakeholder engagement, and sustainability. Data infrastructure was most frequently discussed as problematic in evaluation of surveillance systems (n = 36, 75.0%). The most frequent success to surveillance system implementation was stakeholder engagement (n = 30, 65.2%).

Conclusions

Experiences of AMR surveillance systems are diverse across contexts. There is a distinct separation of experiences between systems with emerging surveillance systems and those with established systems. Surveillance systems require extensive refinement to become representative and meet surveillance objectives.

Journal Reference: Do, P.C., Assefå, Y.A., Batikawai, S.M. et al. Strengthening antimicrobial resistance surveillance systems: a scoping review. *BMC Infect Dis* 23, 593 (2023). <https://doi.org/10.1186/s12879-023-08585-2>

References: SOURCE : BMC Infectious Diseases.

OTC drug policy

Healthcare experts in the country have long been demanding for creating a robust regulatory framework for over-the-counter (OTC) medicines that will enable and facilitate the creation of a positive list of OTC medicines and ensure their widespread availability across the country, including in the remote areas. Experts

Drug News



have also been stressing that this framework should also work towards educating consumers and pharmacists on the judicious use of OTC medicines and the creation of a system of checks and balances regarding the safety, efficacy, promotion, and consumption of such medicines. Even though a separate category for OTC drugs is common in many countries, including developing and developed countries like the US and the European Union, at present India does not have an OTC policy. In India, allopathic drugs which are even safe to be dispensed without prescription mostly fall under Schedule H and H1 and require a prescription.

As per D&C Act 1940 and Rules 1945, these drugs should be sold against prescription only. It is true that a large percentage of people in the country are still not in a position to bear the cost of treatment and the doctor's fee. Once schedule of OTC drugs comes out, the poor patients will have no botheration of visiting doctors for treating common ailments. A qualified pharmacist can then dispense OTC drugs for common ailments such as anti-allergies, antipyretic (for fever), antiemetic (for vomiting and nausea), muscle relaxants, decongestants (for cough and cold), anti-inflammatory, antacids, etc. A robust OTC policy, with clear guidelines for promotion and sale of OTC drugs, will be a win-win situation for both the industry as well as the patients. While it will help the pharma industry grow, for the patients their dependence on medical practitioners for minor ailments will drastically come down, thus saving a substantial amount of money and time.

But, the government should move with caution as a considerable section of patients in the

country still require to be educated on the use and side-effects of OTC drugs. Though the OTC drugs are generally those that are effective for minor ailments and extremely safe to use, there should be some mechanism in place to prevent the indiscriminate sale of these drugs. For this purpose, the point-of-sale should be clearly defined and the labeling norms will have to be adequately revised to make it easier for consumers to read and understand its contents.

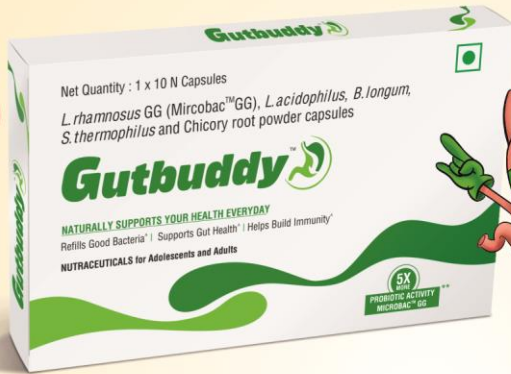
Then there is the issue of similar sounding brand names with different drugs, which should also be addressed by the government before finalising a separate OTC drug category in the country. Some time back, the Organisation of Pharmaceutical Producers of India (OPPI) had conducted a survey 'Value of OTC drugs in India' which revealed that Indians spend around Rs. 36,000 crore annually on treatment of 27 minor ailments including acidity, indigestion, constipation, diarrhea, cold, cough, allergy, headache, joint pain, back ache, body ache, fever, menstrual pain, dental pain, acne, intimate hygiene, cuts/burns/wounds, weakness, tiredness, anemia, eye strain, sleeplessness, smoking control, etc. The study further revealed that healthcare professional spends contributed 86 per cent to the total spends while self-medication accounted for just 10 per cent. The fact is that all these minor ailments can, up to an extent, be treated without consulting a doctor if the country had an OTC drug policy. In a country like India, where the cost of primary healthcare is expensive, a robust OTC drug policy will considerably bring down the cost of primary treatment by providing patients safe, effective and easy access to OTC drug products.

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WHO Recommends R21/Matrix-M Vaccine for Malaria Prevention

The World Health Organization (WHO) has recommended a new vaccine, R21/Matrix-M, for the prevention of malaria in children. The recommendation follows advice from the WHO Strategic Advisory Group of Experts on Immunization (SAGE) and the Malaria Policy Advisory Group (MPAG) and was endorsed by the WHO Director-General following its regular biannual meeting held on 25-29 September.

WHO also issued recommendations on the advice of SAGE for new vaccines for dengue and meningitis, along with immunization schedule and product recommendations for COVID-19. WHO also issued key immunization programmatic recommendations on polio, IA2030 and recovering the immunization programme. The R21 vaccine is the second malaria vaccine recommended by WHO, following the RTS,S/AS01 vaccine, which received a WHO recommendation in 2021. Both vaccines are shown to be safe and effective in preventing malaria in children and, when implemented broadly, are expected to have high public health impact. Malaria, a mosquito-borne disease, places a particularly high burden on children in the African Region, where nearly half a million children die from the disease each year.

Demand for malaria vaccines is unprecedented; however, available supply of RTS,S is limited. The addition of R21 to the list of WHO-recommended malaria vaccines is expected to result in sufficient vaccine supply to benefit all

children living in areas where malaria is a public health risk. “As a malaria researcher, I used to dream of the day we would have a safe and effective vaccine against malaria. Now we have two,” said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. “Demand for the RTS,S vaccine far exceeds supply, so this second vaccine is a vital additional tool to protect more children faster, and to bring us closer to our vision of a malaria-free future.” Dr Matshidiso Moeti, WHO Regional Director for Africa, emphasized the importance of this recommendation for the continent, saying: “This second vaccine holds real potential to close the huge demand-and-supply gap.

Delivered to scale and rolled out widely, the two vaccines can help bolster malaria prevention and control efforts and save hundreds of thousands of young lives in Africa from this deadly disease.” Key features of the R21 malaria vaccine: The updated WHO malaria vaccine recommendation is informed by evidence from an ongoing R21 vaccine clinical trial and other studies, which showed: High efficacy when given just before the high transmission season: In areas with highly seasonal malaria transmission (where malaria transmission is largely limited to 4 or 5 months per year), the R21 vaccine was shown to reduce symptomatic cases of malaria by 75% during the 12 months following a 3-dose series.

A fourth dose given a year after the third maintained efficacy. This high efficacy is similar to the efficacy demonstrated when RTS,S is given seasonally. Good efficacy when given in an age-based schedule: The vaccine showed

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good efficacy (66%) during the 12 months following the first 3 doses. A fourth dose a year after the third maintained efficacy. High impact: Mathematical modelling estimates indicate the public health impact of the R21 vaccine is expected to be high in a wide range of malaria transmission settings, including low transmission settings. Cost effectiveness: At prices of US\$ 2 – US\$ 4 per dose, the cost-effectiveness of the R21 vaccine would be comparable with other recommended malaria interventions and other childhood vaccines. Similarity of R21 and RTS,S vaccines: The two WHO-recommended vaccines, R21 and RTS,S, have not been tested in a head-to-head trial. There is no evidence to date showing one vaccine performs better than the other.

The choice of product to be used in a country should be based on programmatic characteristics, vaccine supply, and vaccine affordability. Safety: The R21 vaccine was shown to be safe in clinical trials. As with other new vaccines, safety monitoring will continue. Next steps for the second recommended malaria vaccine, R21/Matrix-M, include completing the ongoing WHO prequalification which would enable international procurement of the vaccine for broader rollout. At least 28 countries in Africa plan to introduce a WHO-recommended malaria vaccine as part of their national immunization programmes. Gavi, the Vaccine Alliance has approved providing technical and financial support to roll out malaria vaccines to 18 countries. The RTS,S vaccine will be rolled out in some African countries in early 2024, and the R21 malaria vaccine is expected to become available to countries mid-2024.

3D Printed device uses Sweat to detect & Monitor Diabetes

In a significant stride towards simplified detection and management of diabetes, a team of researchers from the Birla Institute of Technology & Science (BITS), Pilani, Hyderabad, has unveiled a ground-breaking approach. By harnessing 3D printing technology, these scientists have devised a portable system capable of analysing glucose and lactate levels from sweat samples. The study, published in Elsevier and supported by the Telangana State Council of Science & Technology (TSCOST), showcased the potential of sweat as a prime analyte, particularly for continuous monitoring of sugar levels in individuals with type 1 and type 2 diabetes.

According to professor Sanket Goel, the device is crafted using a combination of 3D printing, CO2 laser, and graphene-based electrodes. The innovation also involves in-house extraction of graphene by students. "The system's non-invasive nature eliminates the need for blood samples to gauge glucose levels. It can work with blood too. But, the novel innovation is that it takes a sweat sample to detect lactate concentration," Sanket Goel said. The researchers said that the concentration of lactate is deducted by measuring the light intensity as output on a smartphone. "This works on Electrochemiluminescence (ECL).

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reaction takes place and light is generated as output. By measuring the intensity of light, the lactate concentration can be detected," he added. The researchers employed machine learning to determine precise lactate concentrations, crucial for accurate treatment. The team has developed a portable device that connects to smartphones, presenting human metabolite data via a dedicated app. Their ongoing efforts involve creating a wearable version for continuous monitoring. With plans for production in collaboration with a company, the device is anticipated to be available in the market within six to nine months. The expected cost per device in bulk production is estimated to range between Rs 300 and Rs 400.

TB- Free nation

To make India a TB-free nation by the year 2025, the Union Health Ministry has periodically been taking several laudable initiatives. The last few years have seen the country take definitive steps towards the elimination of tuberculosis from the country. The sustained efforts of the National Tuberculosis Elimination Programme have led to an unprecedented increase in TB notifications and significant improvements in timely diagnosis, adherence, and treatment outcomes. But all these efforts are not sufficient to reach the target of eliminating this deadly disease by 2025 as standard treatment regimen is also of considerable significance.

After a gap of nearly 50 years, two new-generation drugs for the treatment of multi-drug resistant tuberculosis (MDR-TB) - bedaquiline and delamanid - were introduced in the world in

the year 2013, giving a new ray of hope to millions of patients suffering from this dreaded disease. And in 2018, WHO placed these new oral drugs in the list of 'priority' drugs for the treatment of MDR-TB. Till then, MDR-TB cases were treated with kanamycin and capreomycin injections, along with another group of drugs called fluoroquinolones. But, these therapies had serious side-effects including hearing loss and kidney ailments. Moreover, patients have to visit a health facility every day for six months to take injections.

It is now established that bedaquiline is the backbone of injection-free regimen for the treatment of tuberculosis. And the original patent of bedaquiline base compound, its salts, isomers and enantiomers has expired on July 18 this year, giving way to other companies to enter into making this medicine. As its original patent was to expire on July 18, 2023, the inventor company Johnson & Johnson (J&J) had filed multiple patents on bedaquiline in India, not limiting itself to the basic compound patent but also filing secondary patents to stake claims on routine improvements and formulations. Fortunately, J&J's efforts to extend secondary patents in India by another 4 years did not bear fruit as the Indian Patent Office rejected its patent extension request in March 2023.

If the subsequent patent for bedaquiline fumarate with a wetting agent is granted, it would have disastrous consequences for the country's ambitious target of eradicating TB by 2025, five years ahead of the world target of 2030. Now, it is time for the Indian government to take some bold decisions to make this wonder

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drug available at affordable prices so that the treatment landscape for patients with MDR-TB can be dramatically transformed for the better.

The government should grab this opportunity by providing support for domestic production of generic anti-TB bedaquiline medicine. This can be a gateway for India's robust generic manufacturing industry to mass produce this medicine and ensure its supplies at affordable prices in all high drug-resistant TB countries worldwide. According to experts, cost of Indian generic bedaquiline is likely to be a fraction of what it costs now. For example, patented anti-HCV medicine was USD 1,000 per tablet and the 84-day course was to cost USD 84,000.



Generic companies initially offered for USD 1000 for a full course and currently it is less than USD 250 for an 84-day

course, 0.3% of patented medicine cost. Around 500,000 people get drug-resistant TB every year globally, and the majority of them are in India. However, less than one-third are able to access treatment. Affordable and quality-assured generic medicines have helped save lives from many diseases and conditions globally. Now with the expired patent on bedaquiline, the Indian government should seize this opportunity to support generic manufacturing so that this wonder drug can reach everyone in need without any further delay.

What is insulin resistance and how to know if you have it?

Insulin resistance is a complex health condition that affects the body's ability to regulate blood sugar levels.

One of the most common lifestyle disorders in India is diabetes. If you've been online for a while now, you may have come across the condition called insulin resistance, mostly associated with diabetes.

Insulin is an important hormone secreted by the pancreas that helps in converting food into energy or storing that energy for later.

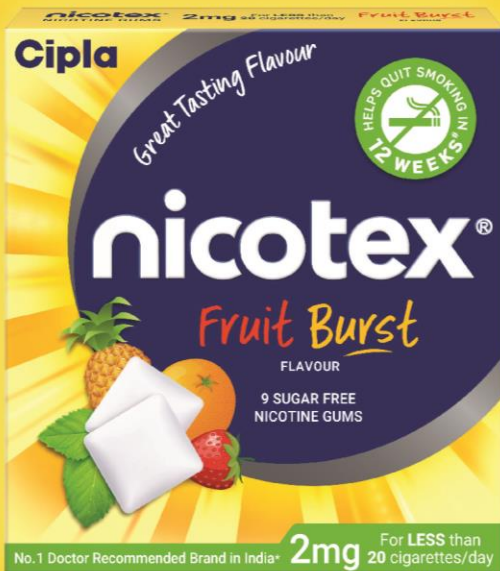
When you have a carbohydrate or sugar-heavy meal your blood glucose levels rise. When this happens, the pancreas responds by producing insulin. The insulin then helps the cells use the sugar and brings the amount of glucose in your bloodstream back to a normal range.

What is insulin resistance?

Insulin resistance is a complex health condition that affects the body's ability to regulate blood sugar levels. It occurs when cells in the muscles, fat and liver do not respond effectively to insulin. This lack of response leads to an increase in blood sugar levels, which can eventually result in prediabetes or type 2 diabetes if left untreated. According to the Centers for Disease and Control (CDC), when a lot of blood sugar enters the bloodstream, the pancreas pumps out more insulin to get blood sugar into cells.

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Dr Himika Chawla, Senior Consultant, Endocrinology and Diabetology at PSRI Hospital, told IndiaToday.in that if your pancreas produces too much insulin, your blood glucose levels may be too low, this condition is known as hypoglycemia.

"Your brain cells may not receive enough glucose to function normally if blood glucose levels fall dangerously low (severe hypoglycemia). This is a serious condition and calls for immediate medical attention," said Dr Himika Chawla.

On the other hand, if your pancreas produces too little insulin, blood glucose cannot enter your cells.

"Your blood glucose level rises as the glucose accumulates until it becomes too high. It is known as hyperglycemia. You might develop type 2 diabetes if your blood glucose levels consistently remain high," said Dr Chawla.

Studies suggest that the fasting blood glucose level between 100 to 125 mg/dL is considered pre-diabetes. If glucose levels remain untreated and become higher than 125 mg/dL, you would be diagnosed with type 2 diabetes.

How do you know if you are insulin resistant?

There are several signs and symptoms associated with insulin resistance. These include high blood sugar levels, high triglycerides (a type of blood fat), high LDL (bad cholesterol), and low HDL (good cholesterol).

Additionally, obesity, particularly excess fat in the abdomen and around the organs, is a

significant cause of insulin resistance. A waist measurement of 40 inches or more for men and 35 inches or more for women is linked to this condition.

Other symptoms of insulin resistance may include increased thirst, frequent urination, increased hunger, blurred vision, headaches, slow-healing cuts and sores and skin changes such as darkened skin in the armpit or back and sides of the neck, and skin tags.

However, it's important to note that many people with insulin resistance may not exhibit any symptoms for years, making it a silent threat to health.

What is the treatment for insulin resistance?

To combat insulin resistance, lifestyle modifications are often recommended. These include losing weight, increasing physical activity and adopting a healthy diet rich in whole foods like vegetables, fruits, whole grains, fish and lean poultry. In some cases, insulin-sensitising medication may also be prescribed by medical practitioners.





NMC VS THE DOCTORS

After receiving criticism from various stakeholders including doctors, pharmaceutical companies and medical devices manufacturers, the National Medical Commission (NMC) has held in abeyance the regulation mandating doctors to prescribe generic drugs. The Commission had earlier issued a notification, asking the doctors across the country to avoid branded generic drugs and prescribe drugs with generic, non-proprietary and pharmacological names only. Justifying its decision, the NMC in its notification said that India's out-of-pocket spending on medications accounts for a major proportion of public spending on healthcare. Further, generic medicines are 30 to 80 per cent cheaper than branded drugs. Hence, prescribing generic medicines may overtly bring down healthcare costs and improve access to quality care.

In the notification, the NMC asked the doctors to advocate for hospitals and local pharmacies to stock generic drugs and prescribe only those generic medicines that are available in the market and accessible to the patient. The NMC further asked the doctors to encourage patients to purchase drugs from Jan Aushadhi Kendras and other generic pharmacy outlets and educate medical students, patients, and the public regarding the equivalence of generic medicine with its branded counterparts. Of course, the intention behind the NMC's move was noble as it shows the Commission's concern over the increasing out-of-pocket expenses of medicines in the country. In a country where prevalence of both infectious and lifestyle diseases are

increasingly impoverishing majority of the population, the government's action was quite justifiable. The medicine cost as a component of treatment procedure for a patient is quite high in India because of the current prescription practice of medical practitioners. The practice among doctors is to prescribe branded generics and sometimes even patented drugs to patients.

While patented drugs are unaffordable to the common man, several branded generics of multinational companies and large Indian companies are also expensive. In such a background, the NMC's move was a welcome one. But, the medical fraternity in the country is up in arms. Vehemently protesting against the NMC's decision, the Indian Medical Association (IMA), the apex body of Indian medical professionals, has urged the government to introduce 'one drug, one quality, one price' system, instead of mandating writing generic names. Raising the issue of quality of drugs, the IMA said that less than 0.1% of the drugs manufactured in India are tested for quality and the biggest impediment of generic drugs is the uncertainty about its quality.

The quality control in the nation being very weak, there is practically no guarantee of the quality of the drugs and prescribing drugs without assured quality would be detrimental to patient health. IMA further stated that if the government is serious about implementing generic drugs, it should give licence only to generics and not to any branded drugs while ensuring quality of generic drugs. It further said that the NMC's decision will shift the onus of exercising the choice of drugs from the doctor to

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the medical shop and now the market forces rather than the profession will determine the choice. Terming the NMC decision as 'running trains without tracks', IMA has now called upon the government to defer the NMC decision till the government can assure the quality of all the drugs released into the market since this directly impacts patient's care and safety. No doubt, any step to promote generic drugs should start from the doctor by making it mandatory to prescribe drugs by their chemical names and break the 'doctor-big pharma' nexus that often leads to prescription of high-cost medicines when cheaper alternatives are available. Apparently, the government has come out with a regulation which was long overdue, but it should lend an ear to the concerns of the medical fraternity too.

Imposing Restrictions on Doctors is an Unhealthy Practice

It is beyond any doubt that nothing can be worse than state intervention in the functioning of professionals and the economy, which are linked to one another. This impact gets evidenced from the recent diktat to medical practitioners that they should prescribe only generic medicines. The Registered Medical Practitioner (Professional Conduct) Regulations 2023 not only mandate prescription of generic drugs but also prohibit doctors from participating in seminars and conferences that have “direct or indirect sponsorships from pharmaceutical companies or the allied health sector.” The regulatory body intends to make healthcare affordable, as generic medicines are 30 to 80 per cent cheaper than branded ones. Not

surprisingly, the Indian Medical Association (IMA) has opposed the newly notified regulations that have been brought in by the National Medical Commission (NMC). The Association has urged the government to withdraw the regulation and enforce them only if it is proven at every level that generic medicines meet quality standards. An IMA, a team of which met Union Health Minister Mansukh Mandaviya recently, is also opposed to the move to bar practicing doctors from participation in seminars and workshops organized by pharmaceutical companies.

It reportedly explained to the Minister that these events provide “opportunities for exchange of knowledge, productive discussions and help doctors and all medical practitioners to stay updated with the prevailing trends.” Promotion of generic medicines and the alleged nexus between medical practitioners and pharma companies are often debated, especially the latter. However, there is hardly any substantial evidence to prove the 'nexus'. In August last year, a NGO had charged Dolo-650 maker Micro Labs that it bribed doctors with freebies worth Rs 1,000 crore in one year to promote the popular antipyretic. The Indian Pharmaceutical Alliance (IPA), an organization of domestic drug makers, did not find any substance in the charge. Its report, released a month later, mentioned that their probe revealed that the allegations were baseless and unwarranted. Yet, Left-leaning NGOs and activists keep screaming about the doctorpharma company nexus all the time. A public interest litigation filed in the Supreme Court sought disciplinary action against doctors who do not prescribe generic alternatives. The views of such bodies and people are the result of

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the dogma that haunts them-all private enterprises are profit-seeking ventures and thus immoral. They are oblivious of the facts, and prefer to remain so. Sadly, such views are rarely checked in the public domain. Even the Narendra Modi government seems to have accepted their discredited and dangerous ideas without scrutinizing them. Equally unfortunate is the fact that the NMC did not elicit views of the crucial stakeholders. There is also an attitudinal issue. Why are doctors and pharmaceutical companies suspected of being innately corrupt? Those who indulge in unscrupulous practices can, and should, be penalized and, if need be, thrown behind bars, but why are all of them seen as potentially unprincipled? Bad ideas and maladroitness generate bad ideas. So, the IMA has advised the government to intervene and reduce the cost of branded medicines. The prescribed remedy is worse than the malady. The government should dump NMC's regulations.

US FDA authorizes Novavax Covid-19 vaccine for use in 12 years of age and above

The US Food and Drug Administration amended the emergency use authorization (EUA) of the Novavax Covid-19 vaccine, adjuvanted for use in individuals 12 years of age and older to include the 2023-2024 formula. Individuals 12 years of age and older previously vaccinated with a Covid-19 vaccine (and who have not already been vaccinated with a recently updated mRNA Covid-19 vaccine) are eligible to receive one dose and unvaccinated individuals receive two doses. The Covid vaccine roll out will soon

include a third option, after the US FDA on Tuesday authorized an updated Novavax shot for emergency use in people age 12 and older.

Novavax's product will be the only non-mRNA Covid-19 vaccine available in the US and could ease logistical issues that have disrupted the roll out amid a surge in new cases. The US FDA authorization was the last regulatory hurdle for Maryland-based Novavax. The updated vaccine is covered under recommendations the Centers for Disease Control and Prevention issued in September. The updated vaccine addresses currently circulating variants to provide better protection against serious consequences of Covid-19, including hospitalization and death. Consistent with the totality of the evidence and input from the FDA's expert advisors, the Novavax Covid-19 Vaccine, Adjuvanted, a monovalent vaccine, has been updated to include the spike protein from the SARS-CoV-2 omicron variant lineage XBB.1.5 (2023-2024 formula).

“The Covid-19 vaccines have saved countless lives and have prevented serious outcomes of Covid-19 caused by the SARS-CoV-2 virus,” said Peter Marks, director of the FDA's Center for Biologics Evaluation and Research. “Today's authorization provides an additional Covid-19 vaccine option that meets the FDA's standards for safety, effectiveness and manufacturing quality needed to support emergency use authorization. As we head into the fall season and transition into 2024, we strongly encourage those who are eligible to consider receiving an updated Covid-19 vaccine to provide better protection against currently circulating variants.”



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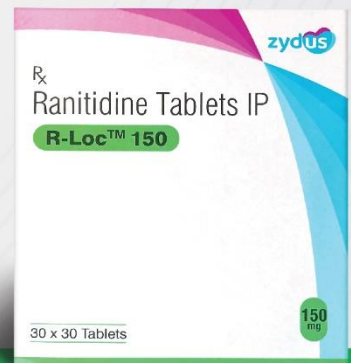
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US FDA Warns Amazon, Walmart & Others For Selling Unapproved Drugs for Viral Skin Infection

The US Food and Drug Administration (FDA) warned retail giants Amazon and Walmart, as well as four other companies, for marketing or distributing unapproved over-the-counter (OTC) products to treat a skin condition called molluscum contagiosum. FDA said an OTC drug for this disease has not been approved and advised these companies to remove the drugs from the market. Other companies cited by FDA include Nature's Innovation Inc, MolluscumRx, Inc.,

Thrasio LLC (d.b.a.ZymaDerm) and Molluscumaway, LLC. FDA sent all six warning letters on 18 August and posted them to its website on 22 August. These warning follows on the heels of a June advisory warning consumers against using over-the-counter drugs to treat molluscum contagiosum, as the agency has not approved any drugs to treat the condition for OTC use. The agency approved the first prescription drug to treat molluscum contagiosum, Verrica Pharmaceuticals' Ycanth (cantharidin) last month.

It's uncommon for FDA to take action against online retailers such as Amazon and Walmart, as they often distribute the drugs on behalf of other sellers who list products on their platforms, yet in this case, Amazon and Walmart were labeled the responsible parties in introducing the drugs into interstate commerce.

The letters to both retail giants state that “your firm is responsible for introducing or delivering for introduction into interstate commerce of these products, which are unapproved new drugs under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the “FD&C Act”), 21 U.S.C. 355(a).” It further notes that “introducing or delivering these products for introduction into interstate commerce is prohibited under sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).”

All six companies were taken to task for marketing unapproved new drugs under section 505(a) of the Federal Food, Drug and Cosmetic Act, and all contained the same boilerplate language stating that “Molluscum contagiosum is not a condition amenable to self-diagnosis and treatment, and there are no legally marketed over-the-counter (OTC) drug products to treat this condition.”

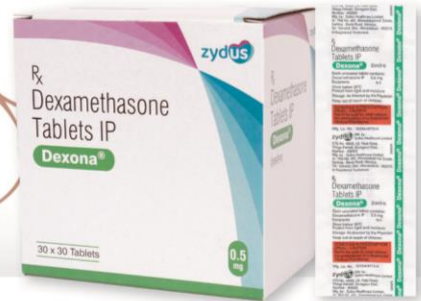
The warning letters gave companies 15 days to describe the steps they are taking to remove these products from the market. The agency further warned that failure to respond “may result in legal action including, seizure and/or injunction.” The warning letter to Amazon's CEO, Andrew Jassy, concerns four products the agency purchased through the company's website, including Naturasil Molluscum Treatment Kit, Conzerol 2 Step Treatment for Molluscum Contagiosum, ZymaDerm for Molluscum and HealthyDerm Molluscum Contagiosum Treatment. FDA stated that all four products are “especially concerning” because they are marketed for use in children. The warning letter to Walmart's also cited the

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company for selling Naturasil Molluscum Treatment Kit on its website.

The remaining warning letters addressed products sold by each company, some of which overlapped with the ones offered by Amazon and Walmart. Molluscumway was cited for offering its MolluscumAway Hydrating Patches, Little Skins Smoothing Skin Ointment and Little Skins Gentle Body Wash products, while MolluscumRX was cited for promoting its MolluscumRx and MolluscumRx Soap products on its website and social media.

One claim made by MolluscumRx stated that “My doctor said it was the best molluscum contagiosum medicine available. And he was right.” FDA’s warning letter to Nature’s Innovation also took issue with the company’s promotion of an unapproved shingles treatment, Naturasil Shingles. “Shingles is a serious condition that is not amenable to either diagnosis or treatment by a lay person, and there are no legally marketed OTC drug products to treat this condition.

Furthermore, FDA is concerned that people who use an unapproved drug product claiming to treat shingles are putting themselves at risk for developing serious complications, e.g., postherpetic neuralgia (long-term nerve pain), herpes zoster ophthalmicus (which can lead to vision loss), and skin infections.”

Prescriptions will Be audited to Reduce Antibiotic Use;

Comprehensive Operational Guidelines Released

Health Minister Veena George has released the SOP for the country’s first block-level antimicrobial resistance committees to prevent overuse of antibiotics in the state. Comprehensive guidelines on the formation, objectives, functions and monitoring of block-level AMR committees have been released. The activities of block-level AMR committees are very important to achieve antibiotic literacy. Major private hospitals will also be made part of the KARSAP (Kerala AntiMicrobial Resistance Strategic Action Plan) network, the minister said.

The Block Level AMR Committee chaired by the Block Medical Officer will have representatives from the Departments of Health, Agriculture, Animal Husbandry, Fisheries, Aquaculture, Food Safety, Pollution Control, IMA, IAP, API, AFPI etc. The main objective of block level AMR committees is to create universal awareness among people, health workers and institutions about proper use of antibiotics and infection control practices.

Awareness should be given on taking antibiotics only as prescribed by an authorized medical officer, the importance of having access to antibiotic-free food and water, and the importance of safely disposing of unused and expired antibiotic medicines. Primary health centres, family health centres, block family health centres, social health centres etc. are targeted to be made into antibiotic-smart



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hospitals. Antibiotic smart hospitals should display AMR awareness posters. All healthcare workers should be trained in infection prevention and control. Expired and unused antibiotics should be disposed of properly. Prescriptions will be audited to assess and reduce unnecessary use of antibiotics. It can also promote generic drugs and reduce polypharmacy. At least 100 prescriptions should be checked every three months.

A minimum of 50 prescriptions per month should be checked randomly in all establishments. The board has directed the Drugs Controller to take steps to display in all pharmacies and medical stores that antibiotics will be dispensed only with a prescription from an approved as per the government directive.

Discussions Underway with Companies over Pricing of Rare Diseases Drugs

The government is actively negotiating pricing of some high-priced drugs used for treatment of rare diseases with pharmaceutical companies including Sanofi, Sarepta and Roche to bring relief to patients who are unable to get treatment due to exorbitant prices of drugs. "Discussions relating to pricing and supplies of medicines with various pharma companies are underway," the government has informed the Delhi High Court that has been hearing a batch of petitions filed by rare disease patients and their caretakers. The court had in May set up a five-member National Rare Diseases' Committee (NRDC) to

implement the Centre's rare diseases policy to ensure that its benefits reach patients.

The panel held discussions with companies involved in research, manufacture and sale of therapies of rare diseases, including Sanofi, Sarepta and Roche, on July 17, the government informed the court earlier this month. NRDC will file a report on the progress made by it in negotiation with companies manufacturing and marketing medicines for rare diseases by the next date of hearing scheduled for September 1, it said. Activists have demanded tax exemption for drugs that are approved by India's drug regulator and are available here. The government counsel informed the court it has flagged the issue over customs duty and GST to the finance ministry and "is hopeful of informing the court about the outcome of the said issue on the next date".

Long-Term Use of Acid Reflux Drugs Linked to Dementia Risk

Prolonged use of acid reflux medications called proton pump inhibitors could increase the risk of dementia, a new study shows. Previous studies gave conflicting advice on whether the medicines were linked to dementia. This latest research, published Wednesday in the journal *Neurology*, found that simply taking a proton pump inhibitor did not necessarily result in a higher risk.



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The key was the amount of time that a person took one of the medicines. The risk showed up after people used the drugs for more than 4 years. People who used proton pump inhibitors for that duration or longer had a 33% greater risk of developing dementia. (The term dementia refers to a group of conditions marked by abnormal and progressive brain changes, the most common of which is Alzheimer's disease.)

Proton pump inhibitors include the drugs esomeprazole, lansoprazole, and omeprazole. Some well-known brand names for these medicines are Nexium, Prevacid, and Prilosec. They work by reducing stomach acid in people whose stomach acid flows into the esophagus, usually after a meal or when lying down.

The condition is called acid reflux and can result in heartburn, ulcers, or a more serious reflux disorder that is linked to cancer of the esophagus. "Proton pump inhibitors are a useful tool to help control acid reflux, however long-term use has been linked in previous studies to a higher risk of stroke, bone fractures and chronic kidney disease," study author Kamakshi Lakshminarayan, MBBS, PhD, of the University of Minnesota School of Public Health, said in a statement.

"Still, some people take these drugs regularly, so we examined if they are linked to a higher risk of dementia. While we did not find a link with short-term use, we did find a higher risk of dementia associated with long-term use of these drugs." For the study, researchers analyzed data for 5,712 people ages 45 years and older who did not have dementia at the start of the study. Their

average age was 75 years old, 22% of them were Black, and 58% were women. The amount of time people were followed during the study varied, but centered around 5 years and 6 months. Of the 4,222 people in the study who did not take the acid reflux drugs, 415 people developed dementia during the follow-up period. Among the 497 people in the study who took the drugs for more than 4.4 years, 58 people developed dementia. Having acid reflux once in a while is common.

A 2019 study estimated that 60 million people in the U.S. have the condition once a month or more. "More research is needed to confirm our findings and explore reasons for the possible link between long-term proton pump inhibitor use and a higher risk of dementia," Lakshminarayan said. "While there are various ways to treat acid reflux, such as taking antacids, maintaining a healthy weight, and avoiding late meals and certain foods, different approaches may not work for everyone. It is important that people taking these medications speak with their doctor before making any changes, to discuss the best treatment for them, and because stopping these drugs abruptly may result in worse symptoms."



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