Look-alike, sound-alike (LASA) drugs in India

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Summary

Poor drug regulation in India is not a recent problem. The Indian drug market is full of look-alike, sound-alike (LASA) drugs which have not yet caught the attention of the media or the medical community. This viewpoint highlights the problem of LASA drugs and poor prescription practices and proposes solutions for involving all stakeholders in this unaddressed issue which is a huge public health problem in India.

Keywords: Health policy; Drug regulation; Look-alike and sound-alike drugs; LASA; Prescriptions

Introduction

Drugs manufactured in India are exported to more than 200 countries. Regulatory lapses in drug production in India recently caught the world's attention. For example, consumption of Indian-origin cough syrups led to deaths in Cameroon, Gambia, and Uzbekistan. Also, in the USA, a type of eye drops manufactured in India was found to be contaminated by *Pseudomonas aeruginosa*.[1–4] However, poor drug regulation in India is not a recent problem as the threshold standard for drug approval is arbitrary.[5] Several issues have been discussed in recently published books *Bottle of Lies*[6] and *The Truth Pill*.[7] In addition to quality issues, India faces major challenges such as proper prescription and dispensing of drugs.

Poorly trained pharmacists, perverse economic incentives, and poor regulatory enforcement have resulted in uncontrolled and unchecked dispensing of drugs in India.[8] Even in cases where the drugs are of standard quality, marketing different drugs with deceptively similar brand names remains a significant problem. Unfortunately, the problem associated with look-alike, sound-alike (LASA) drugs has not caught the attention of the Indian media yet and there has been very little research within the medical and scientific communities about this issue and its impact.

There are critical issues of similar brands for (i) the same drug and (ii) for different drugs causing confusion among doctors, pharmacists, and patients. For example, there are several brands of Molnupiravir such as Cipmolnu, Molnunat, Molflu, Molxvir, Molulife, Molnumize, and Molnutor (the last two manufactured by the same company, Hetero Labs, and both marketed by Torrent Pharma). There is perhaps not much of a risk to patients if similar brand names exist for the same drug manufactured and marketed by different entities. One could argue that incorporating International Nonproprietary Names (INN) would help doctors and pharmacists (despite being prohibited by Section 13 of The Trade Marks Act). However, as per WHO's expert opinion, incorporating INNs endangers the principle that INNs are public property and should not be appropriated by pharma companies by incorporating them into brand names.[9] The issue is that the inclusion of INNs can frustrate the rational selection of further INNs for related substances, which in turn will compromise the safety of patients by promoting confusion in drug nomenclature.

If there is a bigger issue that we should be very worried about it is the same brand name or deceptively similar names for very different drugs. For example, (i) the brand name, 'Olvance' for the antihypertensive drug, Olmesartan, and 'Oleanz', a brand of the antipsychotic drug, Olanzapine. (ii) The brand, IMOX for amoxicillin tablets for humans and INIMOX for a combination of amoxicillin and cloxacillin[10] as an injection for veterinary use. Since there are many brands of amoxicillin + cloxacillin combination in tablet form and for human use, it is possible that a pharmacist will not just dispense but also administer this injection when a doctor prescribes either amoxicillin or the amoxicillin + cloxacillin combination tablets.

There are instances of two different drugs having same name but manufactured and marketed by different entities. For example, (i) brand name 'Medzol' is used for both Midazolam and Pantoprazole; (ii) 'Medzole' is used for Metronidazole oral suspension, Itraconazole capsules and Albendazole tablets; (iii) 'Flucor' is used for both Fluconazole and a combination of Flupentixol and Melitracen; and (iv) 'Linamac' is used

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for both Lenalidomide and Linagliptin.[11] In the case of drugs with identical or similar brand names, there is no way a pharmacist could tell which drug the doctor had prescribed (in general, prescriptions in major parts of India only mention brand names with no mention of diagnosis or treatment protocol). Worse, there is no practical way of working out these 'duplicates' for any researcher, doctor, or pharmacist since there is no publicly accessible database that has all the drugs and the associated brands.

Poor regulatory control has resulted not just in similar-sounding brands of drugs but also similar-looking drugs. For example, GNAP-10 (an anti-hypertensive medication), generic Telmisartan (an anti-hypertensive medication), Glimeimore (an oral hypoglycemic agent), and generic Metoprolol tartrate (a beta-blocker) are manufactured as round white tablets and have almost the same size (Fig. 1). For a patient who cannot read, the shape and colour of the drug and its distinctive packaging are the only clues to identify the drug. Thus, similar-looking drugs in similar packaging make it nearly impossible for patients, especially who do not have an elementary school education, to take their drugs in the prescribed manner.

LASA drugs may lead to significant medication errors and could quite conceivably result in harm to the patients.[12–15] Identical brand names contribute the most to such medication errors.[16] The harm could range from unnecessary drug effects, and side effects to the progression of the disease that was left untreated due to a medication error. In low-income and middle-income countries (LMIC) like India, prevalence of untrained pharmacists also makes LASA drugs a significant public health threat.[12,17]

After judicial directions, Indian law now requires the drug regulatory body to review a trademark search report to ensure there are no misleading brand names, before granting marketing authorisation for a drug.[18] The very existence of countless misleading brand names shows that India's drug regulator, Central Drugs Standard Control Organisation (CDSCO), is not doing what it is tasked to do.[19] The regulator seems to have left it to pharma companies to fight each other in trademark battles to resolve the issue of misleading brand names. Worse, the courts have not been consistent in laying down or applying clear principles, and often these decisions conflict with the basic principles of trademark law.[20] As an example, variations of the brand Viagra, like Penagra and Kamagra have been allowed to be used but only after determining that the pills cannot be the same shape and colour as the rhomboid-shaped blue Viagra pill, even though the pills are in packaging that does not reveal their shape or colour.[21]

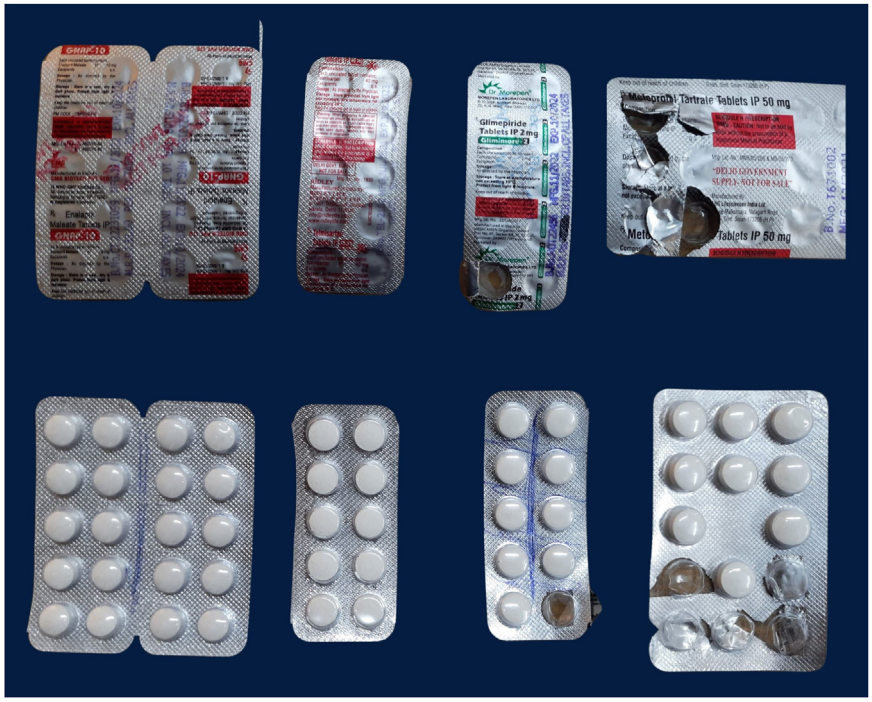

Fig. 1: **Strips of look-alike drugs commonly available in the Indian market: GNAP-10, generic Telmisartan, Gleimeimore, and generic Metoprolol tartrate.** (Generic name of GNAP-10 is enalapril and is marketed by CMG Biotech Private Limited; Telmisartan is marketed by Ridley Life Science Private Limited; generic name of Gleimeimore is glimepiride and is marketed by Morepen Laboratories Limited; Metoprolol tartrate is manufactured by ANG Lifesciences India Limited).

The way forward

Prescription and dispensing errors are rampant in India, but we do not have any clue about the scale of the issue. It is likely to be quite large considering that most prescriptions in India are handwritten lists of brand names and are used multiple times by the patients to buy medicines. Robust data collection on prescription practices and monitoring of prescriptions are required and the ongoing digitalisation of the health system could possibly address prescription errors in the future.

The solutions to medication errors due to LASA drugs could be applied at various levels (Table 1). The only short-term and immediate solution to address the issue of LASA drugs is for the doctors to comply with the guidelines that require them to write in capital letters the INN of the drugs in the prescriptions. After an order by the Odisha High Court, the Odisha government stressed upon the National Medical Commission's (NMC) guidelines and directed all doctors in government and private institutes to write legible prescriptions.[22] However, writing legible prescriptions addresses the problem only partially. It is essential to stress the writing of INNs in the prescriptions which would help the pharmacist to confirm and dispense correct medicines. While this may not eliminate all prescription and dispensing errors, it would be an important step.

Recently, NMC updated its guidelines[23] making generic prescriptions mandatory, and added a penalty for doctors found not to follow these guidelines. However, the updated guidelines were put on hold three weeks after opposition from doctors' national body.[24] To bring in a more realistic change, inspiration could be drawn from prescription models in other countries. For example, financial incentives for writing generic prescriptions are provided to general practitioners in France to boost the generic market.[25] Financial incentives for patients improved generic drug uptake in Greece.[25] In India, improving the awareness of patients regarding the benefits of generic prescriptions, making the addition of INNs in prescriptions mandatory with or without brand names, and penalising doctors who continue to write only brand names or prescribe irrational fixed dose combinations might improve the quality of prescriptions. The proliferation of *Jan Aushadi Kendras* in India—where cheaper single-ingredient drugs are being sold by the government—provides a fertile ground to promote generic prescription writing. However, it is needless to mention the quality of the generic drugs will have to be monitored to gain the trust of the healthcare providers and make generic prescription writing sustainable.

The government should insist that generic medicines would not be approved without conducting Bioavailability and Bioequivalence (BA-BE) studies. Completion of BA-BE studies is a requirement for exported drugs and could be implemented for the generic medicines currently being sold in India.[26] Such

Level of intervention	Intervention
Drug policy level	• Permitting unique brand names for innovator drugs to avoid confusion (currently followed in the USA). • Compulsory use of International Nonproprietary Names (INN) in a prominent manner along with the specific indication for which the drug is prescribed. • Immediate withdrawal of drugs with misleading names. • Uniformity of shapes, colours, and designs for specific types of drugs where misuse can cause serious adverse effects. • Enforcement of pharmacovigilance obligations and tracking prescription and dispensing errors. • Regular updates and advisories on (i) prescription and dispensing errors and (ii) list of misleading names.
Level of drug manufacturing	• Greater emphasis on the quality of drugs, including packaging. • Use of the phonetic and orthographic computer analysis (POCA) tool while deciding brand names. • Use of tall man lettering on drug labels.
Level of healthcare providers	• Listing diagnosis and indications for which specific drugs are being prescribed, in the prescription so that it can be verified at the time of dispensing and any errors can be easily detected. • Strict enforcement of guidelines to promote generic prescriptions making brand names optional to write in prescriptions. • Avoiding distractions while prescribing drugs. • Promoting the use of barcodes to match drugs to patients they are being prescribed for. • Use of computerised drug prescriptions with alert systems. • Use of tall man lettering on prescriptions. • Frequent training to improve prescription writing practices and to update providers on LASA drugs present in the market.
Level of drug dispensing	• Implementing a double-check system to match the drugs prescribed with those dispensed. • Avoiding distractions while dispensing drugs. • Enforcement of the requirement to have a trained pharmacist dispense drugs. • Enforce a requirement to confirm that drug dispensed is appropriate for the indication mentioned in the prescription. • Enforcement action against the sale and dispensing of drugs without valid prescriptions. • Separately storing LASA drugs.
Patient level	• Grant a legal right to patients to obtain a proper prescription from the healthcare provider that describes the diagnosis and medications. • Improving patient health literacy by providing information on the purpose of the prescribed drugs, their alternatives, and possible side effects.

Table 1: **Interventions to reduce look-alike, sound-alike (LASA) medication errors.**

a move would make the doctors more confident in prescribing generic medicines.

The first step, however, to changing the currently prevalent practice is by making sure that the information related to prescription practices—guidelines, regulations, and harm of poor prescription practices on the public—reaches every practicing physician in the country. The Ayushman Bharat Digital Mission maintains a Healthcare Professional Registry.[27] The registry includes practitioners from both modern and traditional systems of medicine. Healthcare providers (HCPs), especially from remote areas, could be encouraged to register on this platform. The government could then use the platform to convey relevant information, notify alerts, and organise periodic online or offline training to keep HCPs updated. National professional bodies too could support their members by updating them frequently using newsletters or bulletins. Frequent training of healthcare professionals and pharmacists in prescription writing and updating them on common LASA drugs in their practice could also help in reducing medication errors. At the same time, regulatory bodies and hospital administration could set guidelines for regular audits of charts to detect and record the prevalence of medication errors due to LASA drugs.

National regulatory bodies and industries could also use the phonetic and orthographic computer analysis (POCA) tool developed by the Food and Drug Administration (USA) in 2002.[28] This tool compares the proposed brand names with other existing brand and generic names and measures the phonetic and orthographic similarities and could help in avoiding the problem of similar-sounding drugs. Bryan and colleagues[12] highlighted other interventions like reducing disturbance during prescription writing, storing LASA drugs separately, tall man lettering, matching patients' drugs using barcodes, and computerised drug orders coupled with patient-specific alerts to avoid LASA drugs-related medication errors. Most importantly, a strong political will along with effective monitoring, enforcement, and evaluation of processes—right from drug manufacturing to drug dispensing—would reduce medication errors and improve patient safety in India.

Contributors

MS, PS: conceptualisation, writing-original draft; AK: writing-review & editing.

Declaration of interests

PS is the founder of Nivarana (www.nivarana.org), a public health information and advocacy platform. Authors have declared no other conflicts of interest.

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