17 July, 2026

To,
The Drugs Controller General,
Central Drugs Standard Control Organisation (CDSCO),
Directorate General of Health Services,
Ministry of Health and Family Welfare, Government of India,
New Delhi-110002

Subject: Comments on CDSCO's Notification inviting comments on brand names being extended to different/changing active pharmaceutical ingredients

This submission presents comments in response to the notification dated 06.07.2026 which invited comments on consideration of the proposal regarding the issue of use of brand name extensions by pharmaceutical firms. The submission is made within the deadline, i.e., 17th July 2026 provided as per the aforementioned notification.

The submission is divided into three parts:

Part A sets out problems posed to public health caused by brand names extension;

Part B proposes our recommendations to address these problems; and

Part C contains two annexures. Annexure 1 lists out indicative examples of the problems we outline in Part A, while Annexure 2 briefly touches upon international perspectives on this issue.

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This submission was made on July 17th 2026 as per the deadline prescribed for comments.

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Part A: Brand Name Extensions' Impact On Public Health

Brand-name extension is the use of an established brand name by pharmaceutical companies for different active pharmaceutical ingredients (APIs) or different fixed-dose combinations. This practice, by pharmaceutical firms, causes confusion and increased chances of medication error.

In India, brand names generally act as the primary identifier using which a doctor prescribes a drug, a patient remembers and requests the drug, or a pharmacist reads, remembers and dispenses the drug.

Brand Name Extensions can lead to at least two distinct types of categories of problematic situations: :

- Type 1: Confusingly Similar Looking/Sounding Drugs (Look-Alike, Sound-Alike / LASA): Different drugs have brand names that look or sound almost the same, for example, Medzole vs. Metzole. Indicatively, whether written format where text looks similar, or packaging design that looks similar, or 'sounds alike' oral requests are made, pharmacists and patients alike are prone to mixing up distinct medicines which may be for completely unrelated causes. Combined with the realities of low English literacy, poor training, messy handwriting, time pressure or dealing with a high patient volume, LASA drugs can cause various types of mix-ups.
- Type 2: Same Brand Name for Distinct Drugs: This could be separate companies that have used the same name for completely different drugs; or it could be the same company that keeps the same name for a 'drug' over time, even as the drug itself actually changes whether due to modification or addition of ingredients including the active ingredients. This poses huge risk especially but not only in Over-The-Counter (OTC) sales, as patients buy OTC drugs, frequently relying on their memory while buying a familiar/known brand, without realizing that the chemical ingredient might have changed.

The State Licensing Authorities, acting under the Drugs and Cosmetics Act, 1940, are concerned with manufacturing safety and formulation stability, not with safety issues that might arise from branding or trade name based causes. This has left a regulatory void over known issues such as the types of problems outlined above.

One instance is of i-Pill. The same manufacturer markets an emergency contraceptive pill as "i-Pill" and a daily birth control pill as "i-Pill Daily".[2] Both the drugs are distinct chemically, and cannot be interchanged: i-Pill is a high dose emergency contraceptive meant for SOS use after unprotected intercourse, while i-Pill Daily is a low-dose hormonal pill meant to be taken daily for a fixed period of time. Since, in India birth control is often bought over-the-counter without a prescription, brand-name confusion can lead to two dangerous outcomes:

1. Severe side effects due to taking the emergency pill daily: If a woman seeking regular daily birth control mistakenly buys the emergency *i-Pill* and takes it frequently, she will subject her body to regular heavy hormone overdose. This will lead to severe hormonal toxicity, heavy menstrual bleeding, and systemic metabolic disorders.
2. Unwanted pregnancy due to taking the daily pill: If a woman who needs immediate emergency contraception mistakenly takes a single dose of *i-Pill Daily*. The low hormone dose will be too weak to stop ovulation, resulting in an unwanted pregnancy.

These instances are not uncommon. Just last week,, (July 2026) Maharashtra FDA seized over 2.45 crores of Aciloc 150+/300+ due to A due to deceptive similarity and dispensing risks associated with Aciloc 150+/300+.[3] There is already an established brand name Aciloc 150/300 with the API Ranitidine, which treats gastric acidity. Aciloc 150+/300+ also treats gastric acidity but the API is replaced by the significantly more potent . Famotidine.

In 2024, the National Human Rights Commission in a suo moto cognizance highlighted the problem of drugs with identical names but prescribed for different ailments.[4] NHRC press release cited the following drugs with identical names but prescribed for different ailments:[5]

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[2] Prashant Reddy T and Dinesh S. Thakur, The Hindu, 'India's problem: different drugs, identical brand names', https://www.thehindu.com/opinion/op-ed/indias-problem-different-drugs-identical-brand-names/article67773569.ec.
[3] Maharashtra FDA bars sale of two Cadila drugs over branding concerns, Economic Times, July 11, 2026; https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/maharashtra-fda-bars-sale-of-two-cadila-drugs-over-branding-concerns/articleshow/132332254.cms
[4] NHRC takes suo motu cognizance of a newspaper article on a large number of drugs being sold in India with identical brand names for treating entirely different ailments, Press Release, Feb 12th 2024, https://nhrc.nic.in/media/press-release/nhrc-takes-suo-motu-cognizance-a-newspaper-article-on-a-large-number-drugs-being-sold-in-india-with-identical-brand-names-for-treating-entirely-different-ailments.
[5] *Id.*

- A drug by the name 'Linamac 5' is used to treat multiple myeloma, a type of cancer, while another drug named 'Linamac' is used to treat diabetes.
- Another medicine being sold under the brand name 'Medzole', is used by four different companies to sell four different active ingredients, treating entirely different medical conditions. The first company uses 'Medzol' to sell a drug containing 'Midazolam', which is used as a sedative. The second company uses the name 'Medzole-DSR' to sell a combination of domperidone and pantoprazole, which is used to treat stomach acidity. A third company uses the name 'Medzole 400' for a formulation containing albendazole that is used in deworming treatment for children. A fourth company uses 'Medzole 200' for a formulation containing Itraconazole, which is a powerful antifungal drug used to treat diseases such as black fungus.

The Annexure 1 provides an indicative (non-exhaustive) list of brand name extensions of medicines, which can have serious adverse effects on the user.

The state of retail medicine dispensing environment further exacerbates the risks.

a. Less than 10% of the Indian population speaks English yet packaging and prescription information of drugs is in English.[6] In such a scenario, a common person recognizes the drug based on how the name sounds, how the package or design looks, or how it reads as, and not what it contains.
b. Regulation of pharmacies is weak in practice, despite clear regulations, drugs which require prescription are regularly dispensed without any prescription.[7]
c. The majority of prescriptions being handwritten or even verbally relayed is recognised as a driver of Look-Alike, Sound-Alike (LASA) error which increases the risk posed by names tending to confuse.[8]

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[6] Prashant Reddy T and Dinesh S. Thakur, The Hindu, 'India's problem: different drugs, identical brand names', https://www.thehindu.com/opinion/op-ed/indias-problem-different-drugs-identical-brand-names/article67773569.ec.
[7] *Id.*
[8] Neelakantan M, Sharma P, Kulkarni A. Look-alike, sound-alike (LASA) drugs in India. Lancet Reg Health Southeast Asia. 2024 May 16;26, https://pubmed.ncbi.nlm.nih.gov/38798984/. Paramathma C. Potential hazards of illegible prescription: look alike sound alike trade and generic names. J Pharm Res. 2015

d. India's pharmaceutical market manufactures over 60,000 generic brands across roughly 60 therapeutic categories,[9] with no dedicated central database of approved trade names against which a new brand name can be checked.

In India, the figures and instances medication error is very high, moreover it has been consistently reported, and researched upon:

- A Delhi specific study found that there were 82 adverse drug instances reported per 1000 outpatient prescriptions.[10]
- An empirical study of prescription orders in a 600-bed teaching hospital in Bihar, found that over 1,500 errors across 28,472 orders were recorded in a period of two years.[11] In the study, it was also observed that 17.46% of the recorded errors (262 of 1,501) were attributed to wrong medication arising from brand or generic name confusion, the second-largest identified cause after dosing errors.[12] A separate study found that incorrect drug selection was responsible for 14% of medical errors.[13]
- A recent systematic literature review evaluated 40 studies looking at patient safety in Indian hospitals from 2014 through April 2025, and found that "medication errors" remain a major threat. The study demonstrated a 34.1% median incidence and an overall error rate of 26.7% in

https://jopcr.com/articles/potential-hazards-of-illegible-prescription--look-alike-sound-alike-trade-and-generic-names. Shankar, R. (2024, April 3). *The issue of identical drug names*. Pharmabiz. https://pharmabiz.com/PrintArticle.aspx?aid=168302&sid=3.

[9] Department of Pharmaceuticals, *Annual Report 2024–25* (New Delhi: Ministry of Chemicals and Fertilizers, Government of India, 2025), https://pharma-dept.gov.in/sites/default/files/Final%20English%202024-25%20AR%20%281%29.pdf.

[10] Bhutada A. Incidence of Medication Error in Critical Care Unit of a Tertiary Care Hospital: Where Do We Stand? Indian J Crit Care Med 2020;24(9):753–754 https://pmc.ncbi.nlm.nih.gov/articles/PMC7584828/.

[11] Manasij Mitra and Maitraye Basu, An Analysis of Medication Errors in a Tertiary Care Teaching Hospital, Journal of Research in Medical and Dental Science, (2020) Volume 8, Issue 3, https://www.jrmds.in/articles/an-analysis-of-medication-errors-in-a-tertiary-care-teaching-hospital-53272.html.

[12] *Id.*

[13] Patel, H., Parthasarathi, G., Shashank, C., Adithyanath, B., Shwetha, D., & Doney, J. (2013). Medication errors—Incidence, causes and possible prevention strategies in Indian health care setting [Abstract]. *Value in Health*, *16*(7), A478.

inpatient settings, with the most common of these medication errors occurring during prescribing (40%) and dispensing/administration (42% combined).[14]

The Ministry of Health and Family Welfare, through the Drugs and Cosmetics (Thirteenth Amendment) Rules, 2019 inserted sub-rule (9) into Rule 71, and added a new Form 51 to Schedule A.[15] This amendment required an applicant proposing a brand name to furnish an undertaking in Form 51 certifying that to the best of their knowledge based on searches across the Trade Marks Registry, CDSCO databases, literature, and the internet, no identical or similar brand name already exists and that the proposed name will not lead to confusion or deception in the market. However, since the mechanism relied entirely on manufacturers' undertaking without any nodal authority to verify the claim, or take any corrective action, confusable look-alike, sound-alike (LASA) names still remain common.

In fact, several committees over the years have flagged issues surrounding brand name extensions, and the need for a centralized framework for approved drugs and formulations:

- The Hathi Committee in 1975 recommended abolition of brand names, in a phased manner, and use of generic names.[16]
- The Mashelkar Committee (2003) which was formed to tackle drug regulatory issues, highlighted a major regulatory flaw: the total absence of a centralized national database of approved formulations and trade names across different state authorities.[17]

[14] Govil D, Khan RA, Agarwal A, Ghosh P. Epidemiology of Medication Errors in Indian Hospital Settings: A Systematic Literature Review. Indian J Crit Care Med. Nov 2025, 29(11), 954-966, https://pmc.ncbi.nlm.nih.gov/articles/PMC12683552/.
[15] G.S.R. 828(E) on 6 November 2019.
[16] Ministry of Petroleum and Chemicals. (1975). *Report of the Committee on Drugs and Pharmaceutical Industry* (Hathi Committee Report). Government of India. https://pharma-dept.gov.in/sites/default/files/Hathi_Committee_report_1975_0.pdf.
[17] Ministry of Health and Family Welfare. (2003). *Report of the expert committee on a comprehensive examination of drug regulatory issues, including the problem of spurious drugs* (Mashelkar Committee Report). Government of India. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=NTk=.

- The Pronab Sen Task Force in 2005 recommended that no change be permitted to the composition of a drug marketed under a given brand.[18]

Each of these recommendations precedes the present notification, and these recommendations could solve the problem underlined in the notification.

The practice of brand name extensions poses a serious threat to patient safety and public health, evidence supporting the same has been earlier discussed as well. It is the critical need of the time to solve this problem.

Brand name extension is not a problem unique to Indian jurisdiction. It is a documented cross-border patient safety failure that WHO and major national regulators like those in the United States of America, Canada, European Union, United Kingdom, and Australia have moved to name, study, and restrict through binding or quasi-binding provisions. For more details refer to Annexure 2: International Perspectives

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Part B: Recommendations to CDSCO

The underlying logic of our recommendations is that a brand name must be permanently associated only with one specific drug, which includes the specific API, as well as specific fixed-dose combination (FDC) as the case may be. Our disclaimer here is that these recommendations are primarily made with chemical drugs in mind. We are not taking a hard stance vis-a-vis biologic drugs in this document as it is possible that they may pose slightly distinct considerations, and would appreciate a chance to give

[18] Department of Chemicals and Petrochemicals. (2005). *Report of the task force to explore options other than price control for achieving the objective of making available life-saving drugs at reasonable prices* (Pronab Sen Committee Report). Ministry of Chemicals and Fertilizers, Government of India. https://pharma-dept.gov.in/sites/default/files/drpronabreport_0.pdf.

further comments on them in the future after some more time to study them as a potentially distinct issue.

Recommendation 1: Permanently Lock Brand Names to a Specific Drug including its specific ingredients

- Reasoning: When a brand name becomes popular, patients, pharmacists and doctors associate that name with a specific drug formulation used for a specific clinical effect. Allowing a company to sell a different chemical formulation under that same name easily misleads the public and creates severe medication risks. A name must serve as a permanent, unchanging identity for a specific chemical formula.
- Proposals:
    1. Amend Rules 71, and 71A of the Drugs and Cosmetics Rules, 1945 to mandate that once a brand name is approved for a specific API or FDC, it cannot be used for any other chemical formula. This rule must apply universally to all manufacturers. If any company changes the active chemical ingredient of a medicine, they must be legally required to register an entirely new brand name. No exceptions can be granted.
    2. Section 17(c) of the Drugs and Cosmetics Act, 1940, deems a drug to be misbranded where its label bears a statement, design or device that is false or misleading in any particular marketing. The law should be clarified to provide that selling a distinct API under a brand name which the public already associates with a different product shall be deemed false or misleading prima facie, thus misbranding.

Recommendation 2: Strictly Regulate the Use of Brand Name Suffixes

- Reasoning: Drug companies often add suffixes like "Plus," "Max," "Active," or "Super" to existing brand names to introduce new ingredients, whether APIs or otherwise.. This practice lends itself to accidental substitution of one drug with the other, posing a threat to patients

who may be sensitive to changes including non-API related changes, or who may no longer be receiving the medicine they think they are receiving due to a changed API.

- Proposal: Issue a statutory notification clarifying that suffixes such as Plus, SR, Active, or Max, can only be used when describing a change in the dosage strength (e.g., 500mg changed to 650mg) or release speed (e.g., Sustained Release / SR) of the exact same active chemical ingredient. Suffixes must be strictly banned from being used when a new active chemical ingredient is added or substituted.

Recommendation 3: Mandate Official Trademark Search Reports and Portal Integration

- Reasoning: In the *Cadila Healthcare Ltd. v. Cadila Pharmaceuticals Ltd. (2001)*, the Supreme Court ruled that medicines require much stricter naming checks than ordinary consumer goods because brand confusion in drugs can lead to fatal poisoning. The Court suggested that the licensing authorities should require an official Trademark Search Report from the applicant, before allowing a drug brand onto the market. Currently, the government tries to prevent confusing names through Form 51 (introduced in the 2019 rules). However, Form 51 is merely a self-declared promise by the drug manufacturer. It fails because state drug authorities do not verify this promise against actual trademark records, and it does not stop a company from reusing their own brand name for different chemical drugs.
- Proposals:
    1. Amendment to Licensing Rules: Amend Rules 71, 71A, 71B, and 76 of the Drugs and Cosmetics Rules, 1945, rules governing manufacturing licenses granted by State Licensing Authorities. The amendment must state that an applicant shall not receive a manufacturing license without submitting an official, verified Trademark Search Report from the Trade Marks Registry proving that the brand name is not confusingly similar to any existing brand name.
    2. Connect Digital Portals: To fix the enforcement gap, the government must link the CDSCO's online filing portal (SUGAM) and the Trade Marks Registry database.

When a manufacturer types a proposed brand name into the SUGAM portal to apply for a manufacturing license, the software should automatically cross-check both trademark registry and existing drug databases. If the system detects a confusingly similar name or an illegal brand extension, the portal should generate a warning to the applicant and flag the application for mandatory manual scrutiny by the State Licensing Authority prior to approval.

Recommendation 4: Redesign Medicine Packaging to Highlight Generic Names on the "Cigarettes' Plain Packaging" Model

- Reasoning: The existing labeling rules under Rule 96 of the Drugs and Cosmetics Rules, 1940 require the generic name or the International Nonproprietary Name (INN) to be printed two font sizes larger than the proprietary brand name. The manufacturers follow the rule, however, they print the larger generic name only once, often across the breakable lines of the strip, thus, it gets torn away when the patient extracts the first few doses. Conversely, the brand name is printed repetitively across the rims and over individual pill pockets. When a patient finishes a strip and presents it to a chemist for a refill without a prescription, only the brand name survives.
- Proposal: Amend Rule 96 (Manner of Labelling) of the Drugs and Cosmetics Rules, 1945, to introduce a two-pronged labeling mandate for both outer boxes and strips/blisters packaging:
    1. The generic chemical name (INN) must occupy at least 80–85% of the main display area on all medicine boxes and cartons in a bold, high-contrast, legible typeface. The proprietary brand name must be restricted to 15–20% of the display area, positioned directly below the generic name.
    2. Rule 96 must mandate repetitive printing of the INN or the generic name on all blister packs and foil strips. The generic name (INN), along with the dosage strength, must be printed continuously across every single unit-dose pocket of the strip. The layout must

guarantee that even if only one pill or a fragment of the strip remains, the generic chemical name is fully intact, legible, and visually prominent over the brand name.

Recommendation 5: Ensuring Better Drug Safety and Quality Monitoring and Consistent Regulatory Scrutiny go Hand in Hand with All Above Efforts.

- Reasoning: Changing the labelling requirements will not fully solve the problem if the doctors, pharmacists and patients fundamentally lack trust in the underlying quality of medicines. In a system where quality of drugs is a known inconsistency, stakeholders will look towards proxy markers of quality, such as brand names, regardless of ground truths. In the Indian healthcare system, reliance on specific proprietary brands of medicines, despite claimed equivalence by other companies, is driven by concerns over irregular drug safety and efficacy checks of the drug, and regulatory inconsistencies. There is a lack of trust that needs to be addressed if stakeholders are to be able to trust regulatory standards rather than proxy signals out of desperation or lack of options.
- Proposal: To effectively curb the influence of brand-name extensions, the CDSCO must also address the root cause of systemic mistrust. Our first level recommendations here are straightforward:
    1. CDSCO must adopt a multi-year plan to harmonize the Good Manufacturing Practices (Schedule M, Drugs and Cosmetics Rules, 1945) across all states and UTs. CDSCO must look to ensure that drug quality standards are strictly enforced and satisfied by the branded and generic manufacturers, with adequate penal provisions as well as public safety provisions such as withdrawal of drugs from the market as required
    2. CDSCO must establish a publicly accessible record about the batch testing data and quality test results of drugs. This would result in a transparent, accountable framework which would certify quality thresholds being attained by the drug manufacturers. This

could then be used to help stakeholders transition away from leaning heavily on proxy signals for quality assurance to generic based drug prescription.

Annexure 1

Indicative Examples of Brand Name Extensions with Potential Adverse Risks.

(Disclaimer: we do not claim any medical expertise and the details mentioned below are as gathered from cited sources and are listed here merely for indicative purposes.)

Example 1:

Linamac (API: Lenalidomide, for cancer)[19]

Linamac (API: Lenagliptin, for Type 2 diabetes)[20]

Linamac D (API: Lenagliptin + Dapagliflozin, for diabetes)[21]

Linamac M (API: Lenagliptin + Metformin, for diabetes)[22]

Example 2:

Taxim-O (API: cefixime, for simple bacterial infections)[23]

Taxim-OF (API: Cefixime + Ofloxacin, for bacterial infections like drug resistant typhoid)[24]

Example 3:

Dolo 650 (API: Paracetamol, for fever)[25]

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[19] Buy Linamac 5mb Capsule, MrMed (last visited July 17, 2026), https://www.mrmed.in/medicines/linamac-5mg-capsule

[20] Linamac Tablet, Tata 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/linamac-tablet-1008234.

[21] Linamac D 10mg/5mg Tablet, Tata 1mg (last visited July 17, 2026), https://www.1mg.com/hi/drugs/linamac-d-10mg-5mg-tablet-913880.

[22] Linamac M 500mg/2.5mg Tablet, Tata 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/linamac-m-500mg-2.5mg-tablet-965329.

[23] Taxim-O 200 Tablet, Tata 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/taxim-o-200-tablet-52001.

[24] Taxim-OF Tablet, Tata 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/taxim-of-tablet-130832.

[25] Dolo 650 Tablet, 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/dolo-650-tablet-74467.

Dolo Cold (API: Paracetamol, Phenylephrine hydrochloride, Chlorpheniramine maleate, and Caffeine, for common cold and allergy symptoms)[26]

Example 4:

Aamin (API: Amlodipine, for hypertension)[27].

Aamin-A (API: Amlodipine + Atenolol, for hypertension and angina)[28]

Example 5:

Alphagan (API: Brimonidine 0.2%, for Glaucoma)[29]

Alphagan P (API: Brimonidine 0.15% + Purite, for Glaucoma)[30]

Example 6:

Ciplox (API: Ciprofloxacin, drops for bacterial infection in eyes or ears)[31]

Ciplox D (API: Ciprofloxacin + Dexamethasone, drops for bacterial infection and inflammation in eyes or ears)[32]vs.

Ciplox OZ (API: Ciprofloxacin + Ornidazole, tablet for bacterial or parasitic infectious gastrointestinal infections, diarrhoea and dysentery.)[33]

Example 7:

Alkeran (API: Melphan, for Ovarian Cancer)[34]

Leukeran (API: Clorambucil, for Leukemia and certain types of lymphoma)[35]

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[26] New Dolo-Cold Tablet, Apollo Pharmacy (last visiteded June 26, 2026), https://www.apollopharmacy.in/medicine/new-dolo-cold-tablet.
[27] Aamin 5mg Tab, MedPlus Mart (last visited July 17, 2026), https://www.medplusmart.com/product/aamin-5mg-tab_aami0001.
[28] Aamin-A 5mg/50mg Tablet, Apollo Pharmacy (last visited July 17, 2026), https://www.apollopharmacy.in/medicine/aamin-a-5mg-50mg-tablet.
[29] Alphagan Eye Drop, Tata 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/alphagan-eye-drop-319965.
[30] Alphagan-P Eye Drop, Tata 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/alphagan-p-eye-drop-48561.
[31] Ciplox Eye/Ear Drops, Tata 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/ciplox-eye-ear-drops-197483.
[32] Ciplox-D Eye/Ear Drops, Tata 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/ciplox-d-eye-ear-drops-63798.
[33] Ciplox OZ Tablet, Tata 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/ciplox-oz-tablet-63799.
[34] Alkeran 2mg Tablet, 1mg (last visited July 17, 2026), https://www.1mg.com/drugs/alkeran-2mg-tablet-17655.
[35] Buy Leukeran (Chlorambucil) 2mg Tablet, GNH India (last updated June 17, 2026), https://www.gnhindia.com/products/leukeran-tablet.

Annexure 2: International Perspectives

1. **WHO Framework:**

   WHO's 2017 Global Patient Safety Challenge: Medication Without Harm set out to halve severe, avoidable medication-related harm within five years, and LASA (look-alike, sound-alike) confusion was identified as one of its core workstreams.[36]

   WHO defines LASA medicines as those confused due to orthographic (look-alike) and phonetic (sound-alike) similarities, arising in brand-brand, brand-generic, and generic-generic pairings alike, meaning WHO treat as a structural naming issue applicable everywhere brand names coexist with generics.[37]

   WHO has also endorsed practical mitigations such as "tall man" (mixed-case) lettering for high-risk name pairs,[38] a low-cost intervention India's proposed solution could draw on directly.

2. **United States – provides a dedicated post-market surveillance project since 2001.**

   The FDA's 2001 Name Differentiation Project specifically evaluated postmarketing confusion reports for name pairs, and its findings fed into what is now a standing pre-market clearance requirement.[39] Under the FDA's December 2020 guidance, Best Practices in Developing Proprietary Names for Human Prescription Drug Products, brand extension is treated as a named, disfavoured category: sponsors are told that reusing a proprietary name already associated with another marketed product has caused patients to be medicated for the wrong indication, in the wrong population, at the wrong dose, or in a contraindicated manner.[40]

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[36] World Health Organization. (2017). *Medication Without Harm: WHO Global Patient Safety Challenge*. Geneva: World Health Organization. (Licence: CC BY-NC-SA 3.0 IGO), https://www.who.int/publications/i/item/9789240058897.

[37] World Health Organisation, Medication safety for look-alike, sound-alike medicines, p. 3-4 https://iris.who.int/server/api/core/bitstreams/5a2f5a2c-e95c-45b8-ad44-f15c9351f9f1/content.

[38] World Health Organisation, Medication safety for look-alike, sound-alike medicines, p. 12 https://iris.who.int/server/api/core/bitstreams/5a2f5a2c-e95c-45b8-ad44-f15c9351f9f1/content.

[39] U.S. Food and Drug Administration. (2001). *Name Differentiation Project*. Center for Drug Evaluation and Research (CDER), Office of Post-Marketing Drug Risk Assessment https://www.fda.gov/media/88496/download.

[40] U.S. Department of Health and Human Services, Food and Drug Administration, CDER & CBER. (2020, December). *Best Practices in Developing Proprietary Names for Human Prescription Drug Products: Guidance for Industry* (Docket No. FDA-2014-D-0622) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry.

Real incidents recorded by the Institute for Safe Medication Practices, such as the Dulcolax brand extending onto a differently-formulated product are cited in FDA's own guidance as the evidentiary basis for this position.

3. **Canada – provides a statutory definition of the exact practice at issue.**
   Health Canada's framework is the most directly on-point for this consultation because it names and defines the precise phenomenon. Under the Food and Drug Regulations, C.01.001(1),[41] a "brand name" is a defined statutory term, and Health Canada's guidance separately defines a "product line extension" as a drug named using the brand name of another drug with an added prefix or suffix meant to distinguish the new product a practice Health Canada records as having arisen specifically as a marketing strategy to exploit the familiarity of the original product name.

   This concern is not new: Health Canada's own files trace regulatory anxiety over LASA brand names back to 1976.[42] Every proposed brand name today undergoes a mandatory LASA assessment, run in coordination with the Institute for Safe Medication Practices Canada, before Health Canada will authorise it.[43]

4. **European Union and United Kingdom – provides name review as a precondition to market entry.**
   EMA's Name Review Group screens every proposed invented name under Guideline EMA/CHMP/287710/2014 (Rev. 7) specifically for confusion "in print, handwriting or speech" with existing products, and treats the addition of a distinguishing qualifier to an existing brand for a new formulation or indication as requiring a fresh marketing authorisation application not a costless extension.[44]

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[41] Government of Canada. *Food and Drug Regulations* (C.R.C., c. 870), Part C, Division 1, s. C.01.001(1).
[42] Issue Analysis Summary: Look-alike Sound-alike (LA/SA) Health Product Names: The Development of a Comprehensive Policy Recommendation for Look-alike Sound-alike (LA/SA) Health Product Names https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/look-alike-sound-alike/issue-analysis-summary-look-alike-sound-alike-health-product-names-development-comprehensive-policy-recommendation-look-alike-sound-alike.html.
[43] Guidance Document for Industry - Review of Drug Brand Names, https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/guidance-document-industry-review-drug-brand-names.html.
[44] Guideline on the acceptability of names for human medicinal products processed through the centralised procedure - Scientific guideline, https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure-revision-7_en.pdf.

Notably, EMA's safety review is deliberately walled off from trademark law: intellectual property rights and trademark registration are expressly outside its remit, confirming that IP protection and medicine-naming safety are treated as separate legal questions in Europe. The UK's MHRA guideline independently flags confusion risk from products sharing a common "umbrella segment" of a brand name, particularly where safety profiles diverge across populations such as pregnancy or renal impairment.[45]

5. **Australia – is treating it as "unacceptable presentation," with a structural fix.**
   The TGA regulates this squarely as "umbrella" or "family" branding and can deem a product's entire presentation legally unacceptable where an established brand name is reused for a product with different active ingredients. Australia has also pursued the structural remedy: since 2016 it has run a multi-year project harmonising Australian ingredient names with WHO's International Non-proprietary Names (INN) system specifically to reduce brand-driven confusion direct precedent for the INN-first approach flagged.[46]

[45] MHRA Guideline For The Naming Of Medicinal Products And Braille Requirements For Name On Label https://assets.publishing.service.gov.uk/media/5a7d4fc640f0b60aaa293abe/naming_of_medicines_guidance.pdf.
[46] Labelling requirements for the International Harmonisation of Ingredient Names project, https://www.tga.gov.au/products/medicines/labelling-and-advertising/medicines-and-biologicals-labelling-and-packaging/labelling-requirements-international-harmonisation-ingredient-names-project; International Nonproprietary Names Programme and Classification of Medical Products, https://www.who.int/teams/health-product-and-policy-standards/inn.