IJPSR (2026), Volume 17, Issue 2 **(Review Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 17 July 2025; received in revised form, 24 September 2025; accepted, 26 October 2025; published 01 February 2026

ME-TOO DRUGS: A REVIEW OF THEIR ROLE AND IMPACT ON HEALTHCARE

Anurag Motwani *, Kiran A. Bhave and Tejal Patel

Department of Pharmacology, HBT MC & Dr. R. N. Cooper Hospital Vile Parle West, Mumbai - 400056, Maharashtra, India.

Keywords:

Me-too drugs, Biosimilars, First-in-class drugs, Regulation, Economic impact

Correspondence to Author:
Anurag Motwani

Junior Resident,
Department of Pharmacology,
HBT MC & Dr. R. N. Cooper Hospital Vile Parle West, Mumbai - 400056, Maharashtra, India.

E-mail: anurag.motwani1@gmail.com

ABSTRACT: Me-too drugs are pharmacologically active compounds that have structural similarities to the first-in-class compound. Approximately 60% of drugs on the World Health Organization's list of essential treatments fall into the "me-too" category. They are an important but contentious component of modern pharmacotherapy, with minor improvements in cost, efficacy, side effects, and compliance on one side of the coin, while on the other side it faces criticism for its growing popularity in a profit-driven development, in absence of new innovation and improper regulatory scrutiny. This review focuses on the primary reasons for the development of me-too drugs whether it is pharmaceutical company driven or actually benefiting patients, as well as the challenges they must overcome, regulatory requirements, differences with the biosimilars and future prospects. We found that me-too drugs have certain limitations in that they lack sufficient innovation affecting new drugs or target development, yet they are considered crucial for expanding treatment options, particularly for patients who cannot tolerate the first-in-class medication.

INTRODUCTION: The term "me-too drug" refers to a pharmaceutical product that is typically similar in structure to an already-approved medication; this could be interpreted as a pharmacologically active compound that shares structural similarities with a first-in-class compound, is considered to be in the same therapeutic class as the original compound, and is used for the same therapeutic purposes. However, there may be some differences, such as the specificity of pharmacological action, the profile of adverse reactions, or drug–drug interactions.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.17(2).408-16

This article can be accessed online on www.ijpsr.com

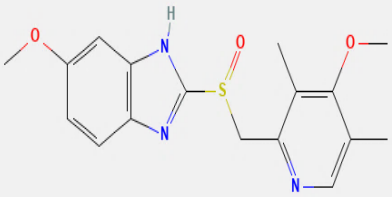
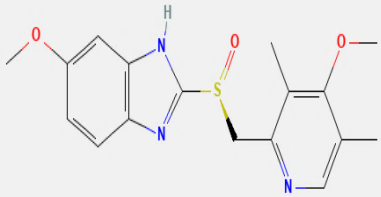
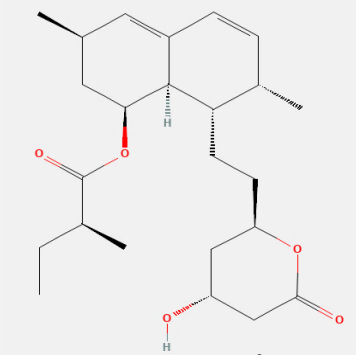
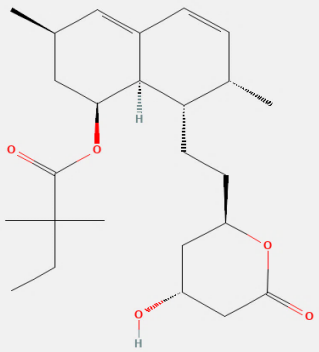
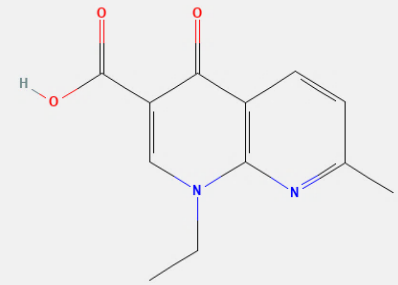
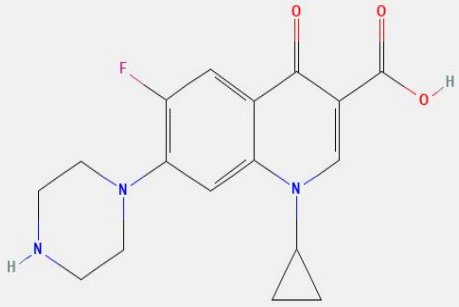
DOI link: https://doi.org/10.13040/IJPSR.0975-8232.17(2).408-16

In 1956, Louis S. Goodman, co-editor of Goodman and Gilman, addressed "the problem of the introduction of me too' drugs, that is, drugs without any signal advantage of any sort [1]." The term Me-too drug is also synonymous with derivative medications, molecular modifications and follow-up drugs [2].

A first-in-class drug is a novel medication with a confirmed target and binding, which is an example of true innovation. Me-too medications seek to enhance the first-in-class medication by, for instance, increasing its potency, lowering its side effects, or providing more convenient dosage (such as oral rather than intravenous), with the ultimate goal of creating a brand-new medication that is regarded as best-in-class. For instance, lovastatin as the first statin became popular as the first of its kind to lower cholesterol levels by inhibiting the enzyme HMG-CoA reductase. However, other me-

too statins which were introduced later, like atorvastatin, is more successful in the marketplace than any other statin [3]. Some me-too drugs are only slightly altered formulations of a company's own drug, packed and promoted apparently offering something new. An example is the gastric acid reducing medication *esomeprazole*, marketed by the same company that makes *omeprazole*. *Omeprazole* is a mixture of two stereoisomers; *esomeprazole* contains only one of the isomers has higher bioavailability and is eliminated less rapidly. Development of *esomeprazole* created a new phase of market exclusivity, although generic versions of *omeprazole* are marketed, as are branded congeners of *omeprazole/esomeprazole*. Both *omeprazole* and *esomeprazole* are now available over the counter-narrowing the previous price difference [2].

TABLE 1: GIVES CERTAIN EXAMPLES OF HOW ME-TOO DRUGS DIFFER FROM THE FIRST-IN-CLASS IN THEIR STRUCTURES-ACTIVITY RELATIONSHIP

First-in class Drug	Me-too Drug	Change in Molecular Structure
Omeprazole [4] 	Esomeprazole [5] 	Esomeprazole is the S-enantiomer. The position of the methoxy group on the benzimidazole ring differs (6-methoxy in omeprazole vs. 5-methoxy in esomeprazole) and chirality at the sulfoxide sulfur atom.
Lovastatin[6] 	Simvastatin [7] 	Simvastatin is 2,2-dimethylbutyrate ester, which is replaced by 2-methylbutyrate ester present in Lovastatin
Nalidixic Acid [9] 	Ciprofloxacin [10] 	Ciprofloxacin differs from nalidixic acid by replacing the ethyl and methyl groups with a cyclopropyl and a fluorine at positions 1 and 6, respectively, and introducing a piperazinyl ring at position 7, while retaining the core quinolone structure

About 60% of drugs on the World Health Organization's list of essential treatments fit into this "me-too" category, and more than 50% of the 50 novel drugs approved by the FDA in 2024 relied on pre-existing targets [10]. Pharmaceutical companies justify the development of me-too drugs by claiming that they provide improvements in cost, efficacy, side effects, and compliance. Sceptics have questioned the growing popularity of me-too(s), their use of R&D funds, and their impact on the development of new treatments [11]. **Fig. 1** highlights the huge difference in the number of publications on first-in-class vs me-too drugs from a Pubmed search. Given this context, it is evident that even though large number of me-too drugs are introduced in market as compared to first in class drug, the number of publications related to first-in-class is much more in number than me-too drugs.

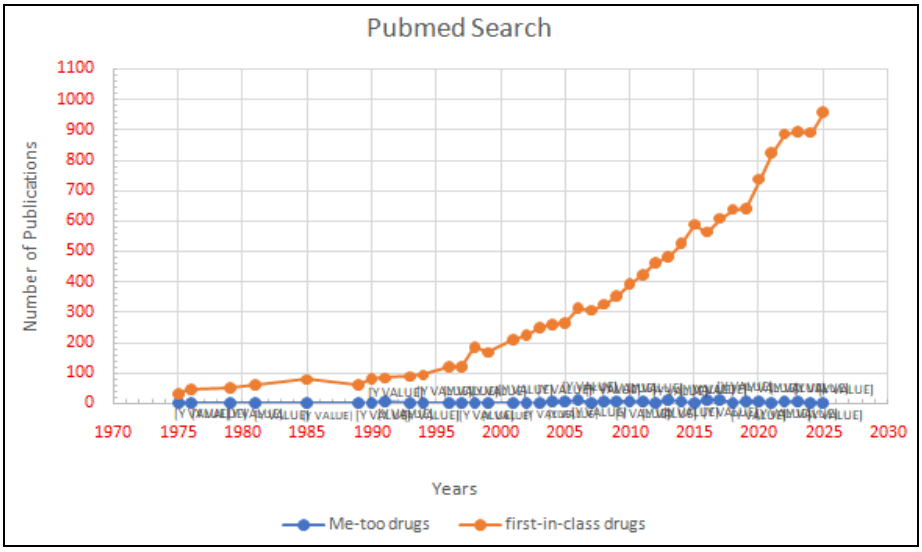


FIG. 1: A PUBMED SEARCH FOR NUMBER OF PUBLICATIONS ON "ME-TOO DRUGS" AND "FIRST-IN-CLASS DRUGS" FROM 1975 TILL JULY 2025 GAVE 141 RESULTS AND 13178 RESULTS RESPECTIVELY

Hence it is essential to investigate the primary reasons for the development of me-too drugs, as well as the challenges that they have to face.

Reasons for Development of Me-Too Drugs:

Financial Benefit to the Company: A company who developed a first-in-class drug has all the target molecule, scientific data and leading to lower cost of R&D for making a me-too drug. Now they just have to screen for the structurally related group of compounds. Not just one but multiple congeners (structurally different) are developed, in case one drug fails the others act as a backup. Also, the staff is already trained for the first-in-class drug, so no further training of staff required for the me-too drug. Hence the financial benefit to company is obvious [12].

Superiority to First-In-Class Drug: Some me-too drugs are better than the parent or first-in-class drug in terms of efficacy, safety and tolerability. Examples include (the drug mentioned former is me-too while latter are first in class):

- Ranitidine vs Cimetidine (more adverse reaction)
- Simvastatin vs lovastatin (less efficacious)
- Escitalopram vs Citalopram (less efficacious) [13]

Improved Pharmacokinetics: Me-too drugs often exhibit improved pharmacokinetics through enhanced bioavailability, prolonged half-life, or optimized metabolism, leading to better efficacy and reduced dosing frequency. Examples include:

Improved Metabolism/Absorption: Acyclovir has poor oral bioavailability (~15-30%). Valacyclovir is a L-valyl ester prodrug with ~55% bioavailability, allowing less frequent dosing and better systemic exposure leading tohigher Cmax (3–5× acyclovir after equivalent dose) [14].

Decreased Frequency of Administration:

- Atorvastatin (OD) vs lovastatin (BD)
- Zoledronate (once yearly) Vs Alendronate (once weekly)
- Semaglutide (once weekly) vs exenatide (twice daily) [15]

Improved Bioavailability:

- Esomeprazole has a higher oral bioavailability (~89% vs. 50-60% for omeprazole), leading to more consistent acid suppression.
- Ciprofloxacin has higher oral bioavailability (~95% vs 50% for nalidixic acid) making it more potent and higher antibacterial activity [16]

Faster Market Entry: Regulatory pathways, such as 505(b) (2) in the U.S., allow for expedited approval using existing data, leading to quicker launches. This helps the pharmaceutical company

to quickly launch a me-too drug, which ultimately leads to faster return on investment [17].

In India, Bioequivalence (BE) and Bioavailability (BA) Studies for Me-Too Drugs needs to be conducted instead of full clinical trials, cutting the approval time significantly [18].

Alternatives for Physicians: Physicians can choose drugs among multiple options from the same class for the same therapeutic indication; taking into consideration the drug with least adverse effect and maximum efficacy, which may or may not be present the first-in-class drug.

Also, in case of parent drug shortage there is an option for using me-too drugs, that is clinically interchangeable, ensuring uninterrupted supply for optimum patient care and treatment outcomes [19].

Challenges with Me-Too Drugs:

Resource Reallocation: Focusing on me-too drugs can divert resources away from the development of truly innovative drug targets (lack of innovation is a key challenge), potentially slowing the advancement of novel therapies [20].

Example: The development of rosuvastatin, a statin introduced after existing options like atorvastatin and simvastatin, involved significant investment. While rosuvastatin demonstrated efficacy in reducing cholesterol levels, its development may have diverted resources from exploring novel lipid-lowering therapies [21].

Economic Impact: Introduction of a second or third compound of the same class into a therapeutic area tends to increase rather than decrease market share, the proliferation of me-too drugs can result in higher healthcare costs without commensurate therapeutic benefits. While they may be cost-effective in the short term, they can raise costs over time [22].

Example: The introduction of esomeprazole, a proton pump inhibitor (PPI), followed the earlier release of omeprazole. Despite esomeprazole's similar mechanism of action, its launch did not lead to reduced healthcare costs. Instead, marketing strategies maintained high prices, increasing overall healthcare expenditures without significant therapeutic advancements [23].

Market Saturation: The introduction of multiple similar drugs can saturate the market, leading to confusion among healthcare providers and patients complicating therapy options [24].

Example: The market for selective serotonin reuptake inhibitors (SSRIs) expanded with multiple similar drugs, including fluoxetine, sertraline, paroxetine, and escitalopram. This proliferation led to challenges for healthcare providers in distinguishing among options, potentially confounding treatment decisions due to minimal clinical differences [25].

Regulatory Scrutiny: Regulatory agencies demand clear justifications for approving me-too drugs over existing therapies.

Example: The approval process for sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor for diabetes, was followed by the introduction of similar agents like vildagliptin and saxagliptin. Regulatory agencies required substantial evidence demonstrating that these subsequent drugs offered distinct advantages over existing therapies, leading to increased scrutiny and, in some cases, delayed approvals [26].

After looking at the reasons and challenges, enlisted below (refer **Table 2**) are certain examples of main drug classes comparing first-in-class drug with year of approval and its corresponding me-too drug that was approved soon after:

TABLE 2: COMPARISON OF ME-TOO DRUGS VS. FIRST-IN-CLASS DRUGS

Category	First-in-Class Drug with approval year	Me-Too Drug with approval year	Comments on me-too
Antineoplastic [27, 28, 29]	Nivolumab (2015) (PD-1/PD-L1 inhibitors)	Tislelizumab (2021)	Engineered to reduce FcγR binding and complement-1q binding, lowers hyperprogression risk.
	Palbociclib (2015, CDK4/6 inhibitor)	Ribociclib (2017)	Less fatigue and financial difficulties, more cardiac side effects
	Imatinib (2001, first TKI)	Dasatinib (2006)	More potent BCR-ABL inhibition, effective in imatinib-resistant CML.

Antimicrobials [30, 31, 32] (Fluoroquinolones, Beta-lactams, Macrolides)	Nalidixic Acid (1962, Fluoroquinolone)	Ciprofloxacin (1987)	Fluorine atom at position number 6, leading to increased potency up to 100 times and better tissue penetration
	Erythromycin (1952, Macrolide)	Clarithromycin (1991)	Improved acid stability, better tissue penetration, longer half-life, category C in pregnancy (erythromycin being category B)
	Ampicillin (1961, Penicillin derivative)	Amoxicillin (1972)	Better oral absorption, less GI disturbance.
Antitubercular [33, 34]	Ethinonamide (1960, mycolic acid synthesis inhibitior)	Prothionamide (1972)	Fewer resistance issues and better tolerability.
	Rifampicin (1967, RNA Polymerase inhibitor)	Rifabutin (1992)	Longer half-life, allows weekly dosing and fewer adverse effects
Antiretroviral [35, 36]	Zidovudine (AZT, 1987, first NRTI)	Didanosine (ddI) (1991)	Used in advanced HIV, has more adverse effects such as pancreatitis and rarely used nowadays.
	Nevirapine (1996, First NNRTI)	Efavirenz (1998)	Fewer drug-drug interaction with, less GI side effects and more CNS side effects
Antifungal [37]	Ketoconazole (1981)	Itraconazole (1992)	Better absorbed, fewer interactions, fewer adverse effects
Antimalarial [38]	Chloroquine (1947)	Hydroxychloroquine (1955)	Less retinal and cardiac toxicity, longer half-life.
Antidiabetic [39]	Liraglutide (GLP-1 Agonist, 2010)	Semaglutide (2017)	Once-weekly dosing, greater reduction in HbA1c, more expensive
Antihypertensive [40]	Captopril (1981, First ACE Inhibitor)	Enalapril (1985)	Prodrug activation, fewer side effects due to removal of sulfhydryl group, longer duration,
Anticoagulant [41]	Ximelagatran (2004, oral DTI)	Dabigatranetexilate (2010)	Prodrug activation, fewer drug interaction, less bioavailable (Ximelagatran discontinued due to hepatotoxicity)
NSAID [42]	Celecoxib (1998)	Rofecoxib (1999)	Withdrawn due to high cardiovascular risk
SSRIs [43]	Fluoxetine (1987)	Sertraline (1991)	Has a shorter half-life, fewer drug interactions, fewer adverse events.
H1 Antihistamines [44]	Diphenhydramine (1946)	Chlorpheniramine (1951)	Less drowsinessdue to lower CNS penetration.
H2 Blockers [45]	Cimetidine (1977)	Ranitidine (1981)	Does not contain the imidazole group and hencehas fewer drug interactions and adverse effects (cimetidine is withdrawn)
Proton Pump Inhibitors (PPIs) [46]	Omeprazole (1988)	Lansoprazole (1995)	Slower onset of action but has faster effect on the relief of symptoms of GERD
Statins [47]	Lovastatin (1987)	Simvastatin (1991)	Extra methyl group hence superior in terms of decreasing lipid fractions. Longer half-life and more potent LDL reduction.
		Atorvastatin (1996)	
PDE-5 Inhibitors [48]	Sildenafil (1998)	Tadalafil (2003)	Longer duration (36 hours vs. 4-6 hours for sildenafil) with improved psychological outcomes, decreased flushing but moremyalgia.

After an overall understanding of me-too drugs, it is also important to differentiate them from *biosimilars*.

Biosimilars: Biosimilars are biological products that are highly similar to an already approved reference biologic, with no clinically meaningful differences in terms of safety, purity, and potency over the course of treatment [49]. Biosimilars are complex, large-molecule drugs derived from living cells or microorganism, which are similarin structure, function, and clinical performance [51].

Difference between Biosimilars and Me-Too Drugs: The me-too drugs are structurally altered forms of proven drugs having minor changes in molecular structure, and they typically aim to improve efficacy, safety, or pharmacokinetics [49]. Both offer several advantages, however neither of them are considered to be new chemical entities (NCEs). Me-too drugs only require structural and clinical comparability evaluations unlike biosimilars which need to undergo all phases of clinical trials [52].

While biosimilars aim to reduce treatment costs and increase accessibility without altering therapeutic efficacy, me-too drugs often compete within a drug class by offering slight improvements in clinical outcomes [50]. Biosimilars offer several advantages over their reference biologics, primarily in terms of cost reduction and accessibility. They promote market competition and are priced 10–35% lower than their reference products, enhancing affordability and improving patient access to essential biological therapies [49]. They contribute to healthcare sustainability by reducing the financial burden of biologic treatments, allowing healthcare resources to be reallocated toward newer and more innovative treatments. Moreover, biosimilars may serve as alternatives for patients who experience hypersensitivity reactions to original biologics due to differences in excipients or delivery devices. Example- the availability of biosimilars for rituximab and trastuzumab has led to innovations like subcutaneous formulations of the originals [50].

Despite these advantages, biosimilars also come with notable disadvantages. Their manufacturing process is complex, which, although cheaper than original biologics, still results in high development costs. Regulatory approval is another challenge, as biosimilars undergo extensive comparability studies rather than the simpler bioequivalence testing required for me-too drugs. Interchange ability and immunogenicity pose a challenge, as slight molecular variations between biosimilars and their reference products may lead to different immune responses and therefore need physician's approval before switching to biosimilars; necessitating long-term pharmacovigilance [51]. Lastly, in spite of the cost benefits physicians and patients may continue to favor the original biologic due to brand trust [52].

The important differences between biosimilars and me-too drugs are given below (refer **Table 3**.)

TABLE 3: COMPARISION OF BIOSIMILARS VS ME-TOO DRUGS

Feature	Biosimilars	Me-too drugs
Definition	Highly similar to an approved biologic with no clinically meaningful differences in safety, purity, or potency	Structurally related to first-in-class drug and are Chemically modified
Manufacturing Process	Complex, living cell-based	Chemical synthesis-based
Regulation Pathway	Approved under 351(k) BPCIA in the U.S., following EMA/WHO biosimilar frameworks globally	Abbreviated approval: often via 505(b)(2) in the U.S.
Clinical Trial	Requires extensive analytical comparability + at least 1 PK/PD and 1 clinical study to demonstrate biosimilarity	Often limited or none; if bioequivalence is shown, clinical trials may not be needed
Immunogenicity studies	Mandatory	Not mandatory
Cost Impact	Reduces healthcare expenses	May not significantly reduce costs
Innovation	No major innovation, maintains efficacy	Often introduces improvements in PK/PD profile

Future Directions:

Strict Regulatory Guidelines: After generic drugs become available in a therapeutic class, the benefits of approving a new me-too drug in the same class are almost certainly outweighed by its downsides. For example, the proton pump inhibitor dexlansoprazole was approved, more than 6 years after generic omeprazole became available. Thus, the approval of me-too drugs raises several questions: are so many agents in a single therapeutic class really needed, particularly when generic drugs are available, and, if not, what should be done about it? This necessitates the need for strict regulatory guideline, FDA can devote public resources to the evaluation of each new me-too drug. An alternative approach is to review me-too drugs through established regulatory norms, such as proving noninferiority or superiority to first in class drug [53].

Artificial Intelligence (AI): Pursuing new targets and therapies is essential to reversing the herding trend, and one of the tools for doing this is AI. Herding or repeated drugs having same targetsand the overall effect of this "me-too" style of innovation sets limits in drug development. AI offers the ability to navigate the vast chemical and biological landscape, uncovering hidden patterns and relationships that traditional methods overlook. By integrating data from genomics, proteomics and

cheminformatics, AI can identify novel targets that have been underexplored, evaluating their potential with remarkable speed and accuracy. For example, AstraZeneca, in collaboration with Benevolent AI, has identified novel targets in chronic kidney disease (CKD) beyond the well-known renin-angiotensin system, opening pathways to treatments focused on kidney fibrosis and inflammation. Hence, with AI new targets can be explored, later that can be used to change structure and produce newer me-too drugs [54].

Improving Access to Medicines: Rapid growth in pharmaceutical expenditures and high prices have greatly hampered access to medicines, especially in developing countries like India [54]. Through efforts to develop me-too drugs, combined with national drug price negotiation and reimbursement policies, developing countries might improve access to more affordable medicines. Locally developed me-too drugs may induce price competition and help to negotiate overall cost of similar internationally-developed products [55].

CONCLUSION: The me-too drugs are pharmacologically comparable to first-in-class drugs and are generally created as substitutes for marginal improvements in efficacy, safety, or pharmacokinetics. Although they are sometimes criticised for lacking sufficient innovation which set limits to the new drug or target development, yet they are considered crucial for expanding treatment options, particularly for patients who cannot tolerate the first-in-class medication. Some me-too medications, like statins and β-blockers, have shown remarkable therapeutic benefits, including better pharmacokinetics and fewer adverse effects.

Apart from this one more reason for the development of me-too drugs is to decrease overall medication cost by increasing market competition. Economically, their development is primarily market-driven, with pharmaceutical companies seeking to capture a share of established therapeutic markets. However, as a result of aggressive marketing strategies, there are concerns that healthcare costs will rise, which contradicts the reason for their development. It is critical to address the me-too mindset, which accepts a minor increase in market share or a portion of another drug's current market share. Additionally, their presence in the market contributes to drug supply stability, preventing shortages and ensuring continued availability of treatment options. Despite these benefits, critics argue that the proliferation of me-too drugs diverts investment away from the development of groundbreaking innovations, potentially slowing progress in drug discovery. On the other hand, they contribute to clinical knowledge by generating additional research and comparative data within their respective drug classes. The overall impact of me-too drugs on healthcare depends on regulatory policies, pricing strategies, and how they are integrated into treatment protocols; making them a vital yet debatable component of modern pharmacotherapy.

ACKNOWLEDGMENTS: We would like to thank the Dr. Prasad R. Pandit, Head of the Department, Department of Pharmacology, HBTMC & R.N. Cooper Hospital, Mumbai.

CONFLICT OF INTEREST: None

REFERENCES:

1. Goodman LS: Report of the Committee on Preliminary Screening of Drugs. In: Cole JO, Gerard RW, eds. Psychopharmacology: Problems in Evaluation. Proceedings of a Conference on The Evaluation of Pharmacotherapy in Mental Illness sponsored by the National Institute of Mental Health, the National Academy of Sciences--National Research Council, and the American Psychiatric Association. September 18-22, 1956. Washington 25, DC: National Academy of Sciences National Research Council 1959: 589 [Cross Ref].
2. Brunton LL, Hilal-Dandan R, Knollmann BC, Goodman & Gilman's: The pharmacological basis of therapeutics. Editors. 13th Ed. New York: McGraw-Hill 2018.
3. Tobert and Jonathan A: “Lovastatin and beyond: the history of the HMG-CoA reductase inhibitors.” Nature reviews. Drug Discovery 2003; 2(7): 517-26. doi:10.1038/nrd1112
4. National Center for Biotechnology Information (2025). PubChem Compound Summary for CID 4594, Omeprazole. Retrieved July 16, 2025 from https://pubchem.ncbi.nlm.nih.gov/compound/Omeprazole.
5. National Center for Biotechnology Information (2025). PubChem Compound Summary for CID 9568614, Esomeprazole. Retrieved July 16, 2025 from https://pubchem.ncbi.nlm.nih.gov/compound/Esomeprazole
6. National Center for Biotechnology Information (2025). PubChem Compound Summary for CID 53232, Lovastatin. Retrieved July 16, 2025 from https://pubchem.ncbi.nlm.nih.gov/compound/Lovastatin
7. National Center for Biotechnology Information (2025). PubChem Compound Summary for CID 54454, Simvastatin. Retrieved July 16, 2025 from https://pubchem.ncbi.nlm.nih.gov/compound/Simvastatin

8. National Center for Biotechnology Information (2025). PubChem Compound Summary for CID 4421, Nalidixic Acid. Retrieved July 16, 2025 from https://pubchem.ncbi.nlm.nih.gov/compound/Nalidixic-Acid
9. National Center for Biotechnology Information (2025). PubChem Compound Summary for CID 2764, Ciprofloxacin. Retrieved July 16, 2025 from https://pubchem.ncbi.nlm.nih.gov/compound/Ciprofloxacin
10. https://www.biospace.com/drug-development/opinion-ai-enables-companies-to-break-from-the-herd-in-drug-development [cited on 2025 July 4]
11. Hollis, Aidan (13 December 2004). "Me-too drugs: is there a problem" (PDF). World Health Organization. S2CID 3142385
12. Patterson, Julie A and Norman V: Carroll. "Should the United States government regulate prescription prices? A critical review." Research in social & administrative pharmacy: RSAP 2020; 16(5): 717-723. doi:10.1016/j.sapharm.2019.06.010
13. Collen MJ, Howard JM, McArthur KE, Raufman JP, Cornelius MJ, Ciarleglio CA, Gardner JD and Jensen RT: "Comparison of ranitidine and cimetidine in the treatment of gastric hypersecretion." Annals of Internal Medicine 1984; 100(1): 52-8. doi:10.7326/0003-4819-100-1-52
14. Jacobson MA: "Valaciclovir (BW256U87): the L-valyl ester of acyclovir." Journal of Medical Virology 1993; 1: 150-3. doi:10.1002/jmv.1890410529
15. Piamsomboon, Chumpol, Prasart Laothavorn, Sopon Saguanwong, Boonsert Chatlaong, Chanarong Nasawadi, Pravit Tanprasert and Kittika Pongsiri: "Efficacy and safety of atorvastatin 10 mg every other day in hypercholesterolemia." Journal of the Medical Association of Thailand = Chotmaihet Thangphaet 2002; 85(3): 297-300.
16. Lind T, Rydberg L, Kylebäck A, Jonsson A, Andersson T, Hasselgren G, Holmberg J and Röhss K: "Esomeprazole provides improved acid control vs. omeprazole in patients with symptoms of gastro-oesophageal reflux disease." Alimentary Pharmacology & Therapeutics 2000; 14(7): 861-7. doi:10.1046/j.1365-2036.2000.00813.x
17. https://www.fda.gov/files/about%20fda/published/Abbreviated-New-Drug-Applications-and-505(b)(2)-Applications-(Final-Rule)-Regulatory-Impact-Analysis.pdf [cited on 2025 July 4]
18. The new drugs and clinical trials rules, 2019 1 GSR 227(Ehttps://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/new_DC_rules/NEW%20DRUGS%20AND ctrS%20RULE,%202019.pdf[cited on 2025 July 4]
19. Andrade Luiz Flavio, Catherine Sermet and Sylvain Pichetti: "Entry time effects and follow-on drug competition." The European journal of health economics: HEPAC: Health Economics in Prevention and Care 2016; 17(1): 45-60. doi:10.1007/s10198-014-0654-9
20. Garattini S: "Are me-too drugs justified?." Journal of Nephrology 1997; 10(6): 283-94.
21. Kleemann Robert, Hans MG Princen, Jef J Emeis, J Wouter Jukema, Ruud D Fontijn, Anton J G Horrevoets, Teake Kooistra and Louis M Havekes: "Rosuvastatin reduces atherosclerosis development beyond and independent of its plasma cholesterol-lowering effect in APOE*3-Leiden transgenic mice: evidence for antiinflammatory effects of rosuvastatin." Circulation 2003; 108(11): 1368-74.
22. FojoTito and Sham Mailankody: Andrew Lo "Unintended consequences of expensive cancer therapeutics the pursuit of marginal indications and a me-too mentality that stifles innovation and creativity: the John Conley Lecture." JAMA Otolaryngology-- Head & Neck Surgery 2014; 140(12): 1225-36. doi:10.1001/jamaoto.2014.1570
23. Wang Xia, Jing-Yuan Fang, Rong Lu and Dan-Feng Sun: "A meta-analysis: comparison of esomeprazole and other proton pump inhibitors in eradicating Helicobacter pylori." Digestion 2006; 73(2-3): 178-86. doi:10.1159/000094526
24. Régnier and Stephane: "What is the value of 'me-too' drugs?." Health Care Management Science 2013; 16(4): 300-13. doi:10.1007/s10729-013-9225-3
25. Brezis and Mayer: "Big pharma and health care: unsolvable conflict of interests between private enterprise and public health." The Israel Journal of Psychiatry and Related Sciences 2008; 45(2): 90-4.
26. Gutka, Hiten J, Yang, Harry, Kakar and Shefali: Biosimilars: Regulatory, Clinical, and Biopharmaceutical Development. Springer 2018; 129. ISBN 978-3-319-99679-0
27. Ferrara Roberto, Biagio Ricciuti, Chiara Ambrogio and Dario Trapani: "The Anti-Programmed Cell Death Protein-1/ Programmed Death-Ligand 1 Me-Too Drugs Tsunami: Hard To Be Millennials Among Baby Boomers." Journal of thoracic oncology: official publication of the International Association for the Study of Lung Cancer 2023; 18(1): 17-20. doi:10.1016/j.jtho.2022.11.001
28. Ahmed Shaaban MH, Elbaiomy MA, Eltantawy A, El-Gilany Abdel-Fattah AH and Shamaa SSA: "Comparing Ribociclib versus Palbociclib as a Second Line Treatment in Combination with Fulvestrant in Metastatic Breast Cancer: A Randomized Clinical Trial." Asian Pacific Journal of Cancer Prevention: APJCP 2024; 25(9): 3039-3049. 1, doi:10.31557/APJCP.2024.25.9.3039
29. Kantarjian H, Shah NP, Hochhaus A, Cortes J, Shah S, Ayala M, Moiraghi B, Shen Z, Mayer J, Pasquini R, Nakamae H, Huguet F, Boqué C, Chuah C, Bleickardt E, Bradley-Garelik MB, Zhu C, Szatrowski T, Shapiro D and Baccarani M: "Dasatinib versus imatinib in newly diagnosed chronic-phase chronic myeloid leukemia." The New England Journal of Medicine 2010; 362(24): 2260-70. doi:10.1056/NEJMoa1002315
30. Sharma D, Patel RP, Zaidi STR, Sarker MMR, Lean QY and Ming LC: "Interplay of the Quality of Ciprofloxacin and Antibiotic Resistance in Developing Countries." Frontiers in pharmacology 2017; 8: 546. doi:10.3389/fphar.2017.00546
31. Amsden GW: "Erythromycin, clarithromycin, and azithromycin: are the differences real?." Clinical Therapeutics 1996; 18(1): 56-72; discussion 55. doi:10.1016/s0149-2918(96)80179-2
32. Gordon C, Regamey C and Kirby WM: "Comparative clinical pharmacology of amoxicillin and ampicillin administered orally." Antimicrobial agents and Chemotherapy 1972; 1(6): 504-7. doi:10.1128/AAC.1.6.504.
33. Gupta DK, Mital OP, Agarwal MC, Kansal HM and Nath S: "A comparison of therapeutic efficacy and toxicity of ethionamide and prothionamide in Indian patients." Journal of the Indian Medical Association 1977; 68(2): 25-9.
34. Horne DJ, Spitters C and Narita M: "Experience with rifabutin replacing rifampin in the treatment of tuberculosis." The international journal of tuberculosis and lung disease. The Official Journal of the International Union against Tuberculosis and Lung Disease 2011; 15(11): 1485-9, i. doi:10.5588/ijtld.11.0068.

35. Dolin R, Amato DA, Fischl MA, Pettinelli C, Beltangady M, Liou SH, Brown MJ, Cross AP, Hirsch MS and Hardy WD: "Zidovudine compared with didanosine in patients with advanced HIV type 1 infection and little or no previous experience with zidovudine. AIDS Clinical Trials Group." Archives of Internal Medicine 1995; 155(9): 961-74.
36. Bhatt NB, Baudin E, Meggi B, da Silva C, Barrail-Tran A, Furlan V, Grinsztejn B, Bonnet M and Taburet AM: ANRS 12146/12214-CARINEMO Study Group. Nevirapine or efavirenz for tuberculosis and HIV coinfected patients: exposure and virological failure relationship. J Antimicrob Chemother 2015; 70(1): 225-32. doi: 10.1093/jac/dku348. Epub 2014 Sep 18. PMID: 25239466; PMCID: PMC4267502.
37. Rubino DM, Greenway FL, Khalid U, O'Neil PM, Rosenstock J, Sørrig R, Wadden TA, Wizert A and Garvey WT: "Effect of Weekly Subcutaneous Semaglutide vs Daily Liraglutide on Body Weight in Adults With Overweight or Obesity Without Diabetes: The STEP 8 Randomized Clinical Trial." JAMA 2022; 327(2): 138-150. doi:10.1001/jama.2021.23619.
38. Stokkermans TJ, Falkowitz DM and Trichonas G: Chloroquine and Hydroxychloroquine Toxicity. [Updated 2024 Jan 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537086/
39. Marso SP, Bain SC, Consoli A, Eliaschewitz FG, Jódar E, Leiter LA, Lingvay I, Rosenstock J, Seufert J, Warren ML, Woo V, Hansen O, Holst AG, Pettersson J and Vilsbøll T: "Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes." The New England Journal of Medicine 2016; 375(19): 1834-1844. doi:10.1056/NEJMoa1607141.
40. Vertes V and Haynie R: "Comparative pharmacokinetics of captopril, enalapril, and quinapril." The American Journal of Cardiology 1992; 69(10): 8-16. doi:10.1016/0002-9149(92)90276-5.
41. Shantsila E and Lip GYH: Non-Vitamin K Antagonist Oral Anticoagulants: A Concise Guide [Internet]. Cham (CH): Adis; 2016. Chapter 2, Direct Thrombin Inhibitors. Available from: https://www.ncbi.nlm.nih.gov/books/NBK500199/ doi: 10.1007/978-3-319-25460-9_2
42. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/vioxx-rofecoxib-questions-and-answers[cited on 2025 July 14)
43. Aguglia E, Casacchia M, Cassano GB, Faravelli C, Ferrari G, Giordano P, Pancheri P, Ravizza L, Trabucchi M and Bolino F: "Double-blind study of the efficacy and safety of sertraline versus fluoxetine in major depression." International Clinical Psychopharmacology 1993; 8(3): 197-202. doi:10.1097/00004850-199300830-00010
44. Farzam K, Sabir S and O'Rourke MC: Antihistamines. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK538188/
45. Jensen RT, Collen MJ, McArthur KE, Howard JM, Maton PN, Cherner JA and Gardner JD: "Comparison of the effectiveness of ranitidine and cimetidine in inhibiting acid secretion in patients with gastric hypersecretory states." The American Journal of Medicine 1984; 77(5): 90-105.
46. Janczewska I, Sagar M, Sjöstedt S, Hammarlund B, Iwarzon M and Seensalu R: "Comparison of the effect of lansoprazole and omeprazole on intragastric acidity and gastroesophageal reflux in patients with gastroesophageal reflux disease." Scandinavian Journal of Gastroenterology 1998; 33(12): 1239-43. doi:10.1080/00365529850172304
47. Farmer JA, Washington LC, Jones PH, Shapiro DR, Gotto AM and Mantell G: "Comparative effects of simvastatin and lovastatin in patients with hypercholesterolemia. The Simvastatin and Lovastatin Multicenter Study Participants." Clinical therapeutics 1992; 14(5): 708-17.
48. Gong B, Ma M, Xie W, Yang X, Huang Y, Sun T, Luo Y and Huang J: "Direct comparison of tadalafil with sildenafil for the treatment of erectile dysfunction: a systematic review and meta-analysis." International Urology and Nephrology 2017; 49(10): 1731-1740. doi:10.1007/s11255-017-1644-5.
49. de Mora and Fernando: "Biosimilars: A Value Proposition." BioDrugs: clinical immunotherapeutics, Biopharmaceuticals and Gene Therapy 2019; 33(4): 353-356. doi: 10.1007/s40259-019-00360-7.
50. Weise M, Bielsky MC, De Smet K, Ehmann F, Ekman N, Narayanan G, Heim HK, Heinonen E, Ho K, Thorpe R, Vleminckx C, Wadhwa M and Schneider CK: "Biosimilars-why terminology matters." Nature Biotechnology 2011; 29(8): 690-3. doi:10.1038/nbt.1936.
51. The US Biosimilars Act Challenges Facing Regulatory Approval Cecil Nick PAREXEL Consulting, Uxbridge, Middlesex, UK, Pharm Med 2012; 26(3): 145-152. 1178-2595/12/0003-0145/$49.95/0 Adis [a] 2012 Springer International Publishing AG. All rights reserved.
52. Thill M, Thatcher N, Hanes V and Lyman GH: "Biosimilars: what the oncologist should know." Future oncology (London, England) 2019; 15(10): 1147-1165. doi:10.2217/fon-2018-0728.
53. Gagne, Joshua, Choudhry and Niteesh: How Many "Me-Too" Drugs Is Too Many?. JAMA: the journal of the American Medical Association 2011; 305: 711-2. 10.1001/jama.2011.152.
54. https://blogs.worldbank.org/en/opendata/world-bank-country-classifications-by-income-level-for-2024-2025 [cited on 72025 July 14]
55. Luo Z, Gyawali B, Han S, Shi L, Guan X and Wagner AK: "Can locally developed me-too drugs aid price negotiation? An example of cancer therapies from China." Seminars in Oncology 2021; 48(2): 141-144. doi:10.1053/j.seminoncol.2021.03.001.

How to cite this article:
Motwani A, Bhave KA and Patel T: ME-Too drugs: a review of their role and impact on healthcare. Int J Pharm Sci & Res 2026; 17(2): 408-16. doi: 10.13040/ijpsr.0975-8232.17(2).408-16.