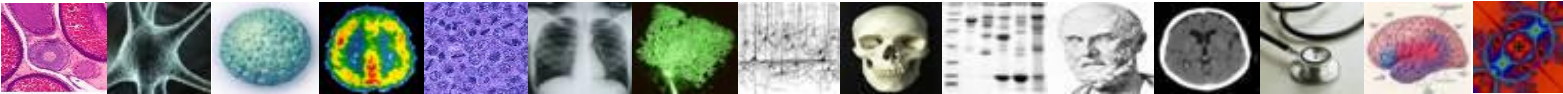


1/15

Los medicamentos genéricos en la literatura indexada internacional

Diego Rosselli M.D., Ed.M., M.Sc.



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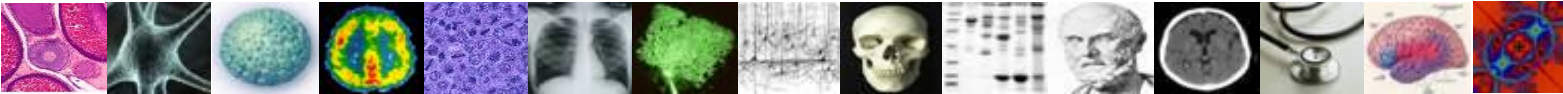
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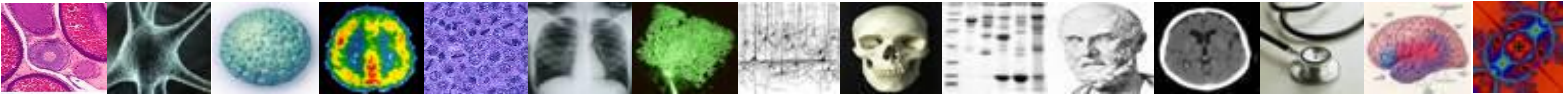
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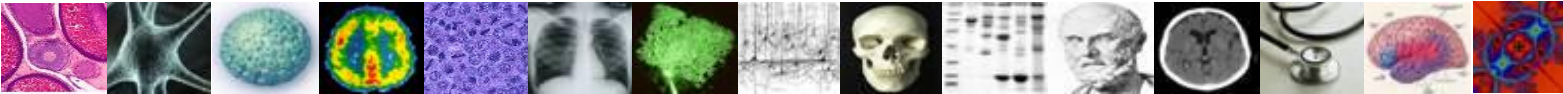
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- ☐ [Medicaid payment for generic drugs: achieving savings and access.](#)
1. Peters CP.
Issue Brief Natl Health Policy Forum. 2010 Sep 30;(839):1-16.
PMID: 20928958 [PubMed - indexed for MEDLINE]
[Related citations](#)
- ☐ [Does antidepressant step therapy fuel the law of unintended consequences?](#)
2. Greden JF.
Am J Psychiatry. 2010 Oct;167(10):1148-51. No abstract available.
PMID: 20889657 [PubMed - indexed for MEDLINE]
[Related citations](#)
- ☐ [Bioequivalence study of two generic formulations of 10 mg montelukast tablets in healthy Thai male volunteers.](#)
3. Sripalakit P, Maphanta S, Saraphanchotiwitthaya A.
Int J Clin Pharmacol Ther. 2010 Sep;48(9):628-32.
PMID: 20860917 [PubMed - indexed for MEDLINE]
[Related citations](#)
- ☐ [The march of the generics.](#)
4. Wyllie MG.
BJU Int. 2009 Oct;104(7):1017-8. No abstract available.
PMID: 20854606 [PubMed - indexed for MEDLINE]
[Related citations](#)
- ☐ [Pharmaceutical quality of nine generic oral statin products compared with Xenical\(r\)](#)

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Generic antiepileptic drugs: current controversies and future directions [Epilepsy Curr. 2008]

Risks and benefits of **generic** antiepileptic drugs. [Neurologist. 2008]

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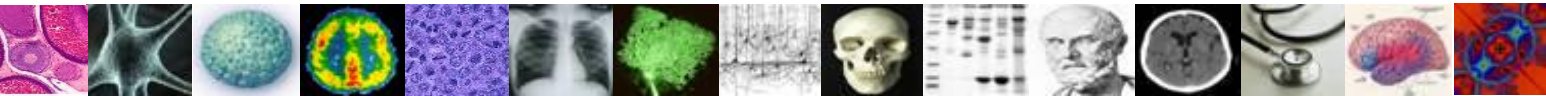
The impact of generic clopidogrel bisulfate on platelet inhibition in patients with acute coronary syndrome [Korean J Intern Med. 2010]

In vitro and in vivo comparison of the anti-staphylococcal efficacy of generic rifampin [BMC Infect Dis. 2010]

Determination of therapeutic equivalence of generic products of gentamicin [PLoS One. 2010]

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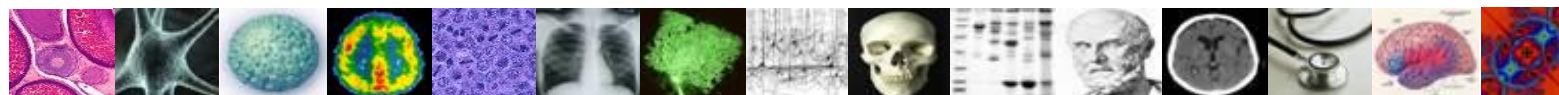
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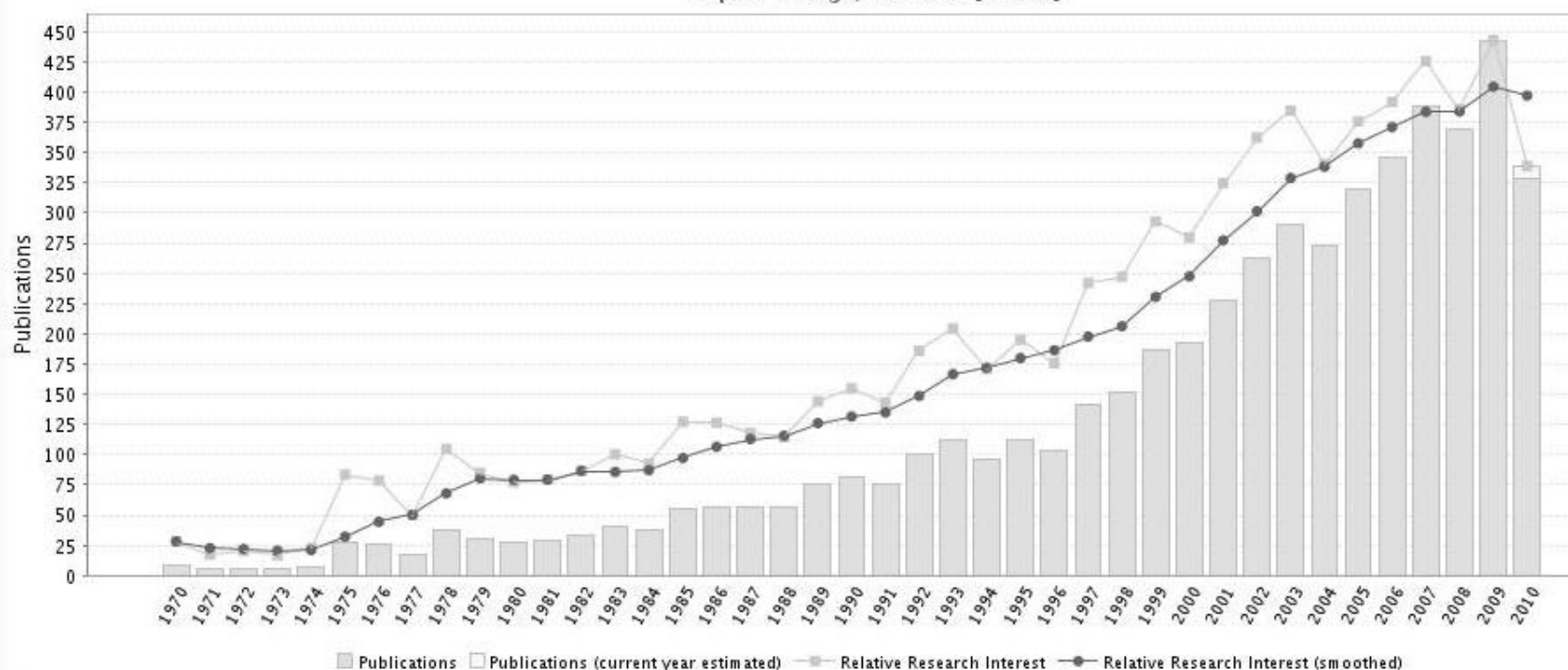
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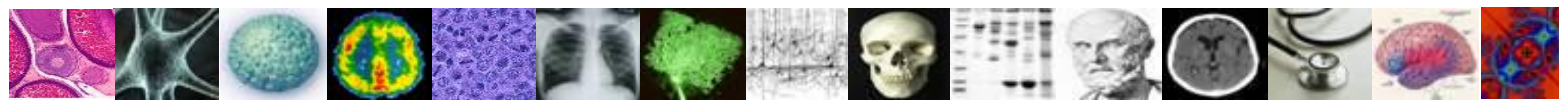




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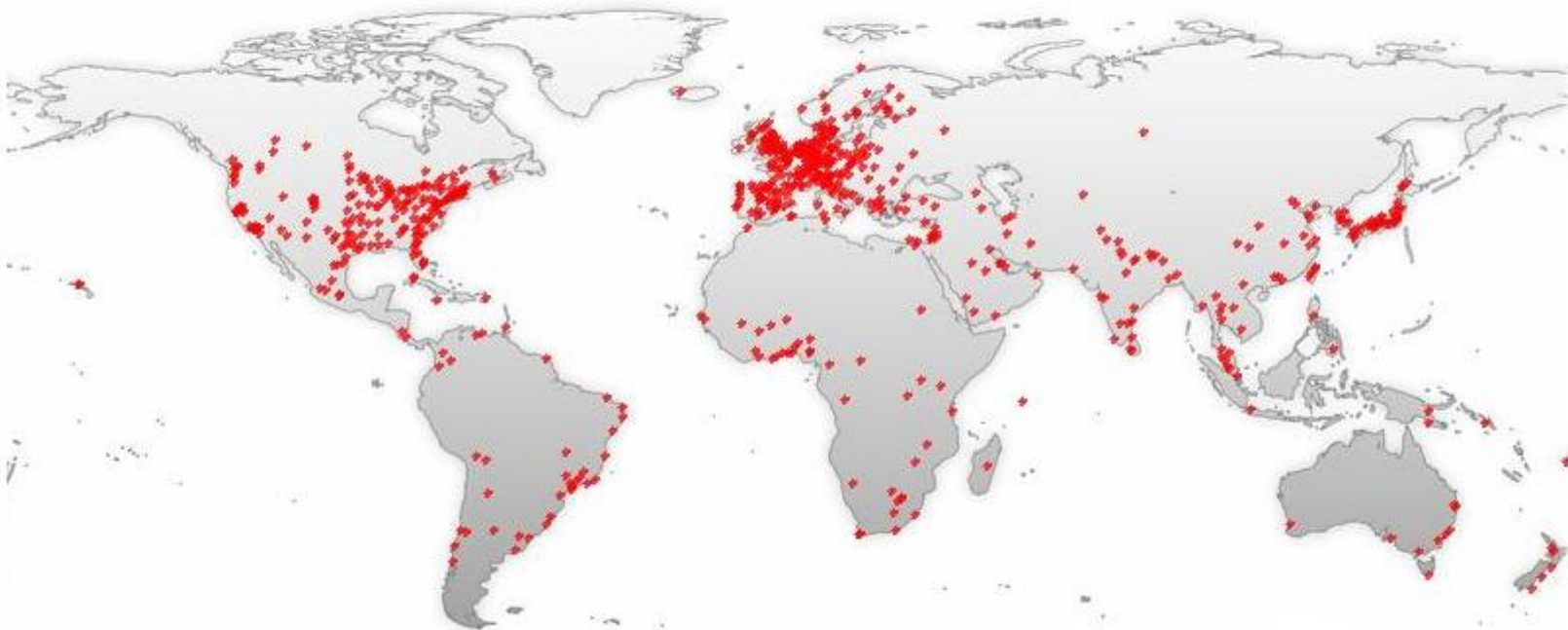
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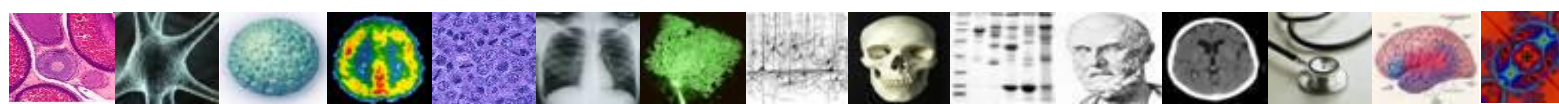
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 Turkey		8
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Prog Neuropsychopharmacol. 1979;3(1-3):297-301.

Ethical aspects of psychopharmacology.

Leon CA.

Unidad de Salud Mental, Hospital Universitario Cali, Columbia.

Abstract

1. A series of topics are presented for the purpose of eliciting discussion and clarification of issues. These include parameters on the ethical implications of: a. Psychopharmacological research in human subjects with special emphasis on the use of placebo for drug trials and problems related to the choice of research methods. b. Prescription of psychotropic drugs, the role of physicians, and the problem of the delegation of functions to para-medical personnel. c. The administration of psychotropic drugs: Issues related to informed consent of the patient, side effects, and groups at special risk. d. Availability and cost of drugs, generic and trade name preparations, as well as selective use of drugs for different populations. 2. Special reference is made to points contained in the "Declaration of Hawaii" (1978).

PMID: 400988 [PubMed - indexed for MEDLINE]

Am J Trop Med Hyg. 2004 Nov;71(5):577-81.

Comparison of generic to branded pentavalent antimony for treatment of new world cutaneous leishmaniasis.

Soto J, Valda-Rodriguez L, Toledo J, Vera-Navarro L, Luz M, Monasterios-Torrico H, Vega J, Berman J.

Consortio de Investigaciones Bioclinicas, Calle 60 A 5-54, Suite 201, Bogota, Colombia. jaime.soto@cable.net.co

Erratum in:

Am J Trop Med Hyg. 2005 Mar;72(3):359.

Abstract

The cost of generic pentavalent antimony (generic stibogluconate) is approximately one-sixth that of branded pentavalent antimony (stibogluconate in the form of Pentostam or meglumine antimoniate in the form of Glucantime). We compared generic stibogluconate to Pentostam and Glucantime for the treatment of cutaneous leishmaniasis patients in Bolivia and Colombia. For all 114 patients, the per-protocol cure rates were 83-91% and the intent-to-treat cure rates were 75-83%. The highest values were in the generic stibogluconate group. The incidence of pancreatic enzyme abnormalities was 48-88% and the incidence of liver enzyme abnormalities was 48-87%. The lowest incidences were in the generic stibogluconate group. The efficacy and tolerance of inexpensive generic stibogluconate appears comparable to branded formulations for the treatment of cutaneous leishmaniasis in these endemic regions.

Biomed Pharmacother. 2009 Jul;63(6):436-41. Epub 2008 Sep 16.

Characterising vancomycin's immunotoxic profile using Swiss and CFW mice as an experimental model.

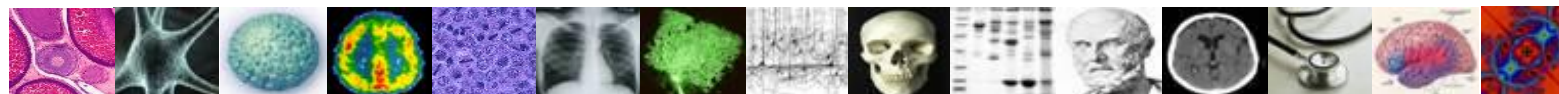
Salguero E, Plaza D, Mariño A, Moreno C, Delgado G.

Immunotoxicology Research Group, Pharmacy Department, Science Faculty, Universidad Nacional de Colombia, Bogotá, Colombia.

Abstract

Immunotoxicology can lead to determining the adverse effects of different compounds on the immune system. Sometimes, many drugs (especially antibiotics) induce immune alterations, mainly auto-immunity. This study was aimed at determining vancomycin's immunotoxic effect by comparing the original molecule to two of the most used copies. Thirty-two mice from two murine strains (Swiss and CFW) were treated with three antibiotic formulations for studying its effect on splenic lymphoid and peripheral blood cell populations by using haemograms, flow cytometry and blastogenesis assays. The results indicated that vancomycin produces neutropenia and lymphocytosis in peripheral populations and that it induces a selective immunomodulatory effect on splenocyte sub-populations, depending on formulation and the strain so treated.

PMID: 18848766 [PubMed - indexed for MEDLINE]



BMC Clin Pharmacol. 2009 Jan 16;9:1.

Application of microbiological assay to determine pharmaceutical equivalence of generic intravenous antibiotics.

Zuluaga AF, Agudelo M, Rodriguez CA, Vesga O.

Grupo Investigador de Problemas en Enfermedades Infecciosas, University of Antioquia, Medellín, Colombia. andreszuluaga@une.net.co

Abstract

BACKGROUND: Demonstration of equivalent amounts of the same active pharmaceutical ingredient (API) between generic and innovator products (pharmaceutical equivalence) is a basic requirement of regulatory agencies for intravenous generic drugs prior to clinical use, and constitutes the pivotal point to assume therapeutic equivalence. Physicochemical methods are preferred instead of biological assays to determine concentration of drugs in biological fluids, but it does not permit direct quantification of potency. Here, we report a microbiological assay using large plates designed to determine potency and concentration of pharmaceutical-grade antibiotics for injection and a statistical method to assess the in vitro equivalence of generic products with respect to the innovator.

METHODS: The assay is based on the concentration-dependent variation of the inhibitory effect of antibiotics on reference bacteria (*B. subtilis* ATCC 6633, *S. aureus* ATCC 6538p and *S. epidermidis* ATCC 12228) in a seeded agar (Difco Antibiotic Media), producing a concentration-response linear relationship with two parameters: y-intercept (concentration) and slope (potency). We compared the parameters of 22 generic products (amikacin 4, gentamicin 15, and vancomycin 3 products) against the innovator and the reference powder by Overall Test for Coincidence of the Regression Lines (Graphpad Prism 5.0).

RESULTS: The validation method yielded excellent results for linearity ($r(2) \geq 0.98$), precision (intra-assay variation $\leq 11\%$; inter-assay variation $\leq 10\%$), accuracy, and specificity tests according to international pharmacopoeial requirements. Except for one generic of vancomycin that had 25% more API ($P(\text{y-intercept}) = 0.001$), the pharmaceutical equivalence was demonstrated in 21 generics with undistinguishable slopes and intercepts ($P > 0.66$). Potency estimates were 99.8 to 100.5, 99.7 to 100.2 and 98.5 to 99.9% for generic products of amikacin, gentamicin and vancomycin, respectively.

CONCLUSION: The proposed method allows rapid, cost-saving, precise, and accurate determination of pharmaceutical equivalence of drugs in pharmaceutical dosage-form, and may be used as a technique for testing generic antibiotics prior to their approval for human use.

J Infect. 2009 Oct;59(4):277-80. Epub 2009 Aug 19.

Potential therapeutic failure of generic vancomycin in a liver transplant patient with MRSA peritonitis and bacteremia.

Rodriguez CA, Agudelo M, Cataño JC, Zuluaga AF, Vesga O.

GRIFE: Grupo Investigador de Problemas en Enfermedades Infecciosas, University of Antioquia Medical School, Medellín, Colombia.

Abstract

We report a case of generic vancomycin treatment failure in a liver transplant patient with MRSA peritonitis and bacteremia, followed by a rapid sterilization of blood and peritoneal fluid after switching to the branded product. It raises concern about therapeutic equivalence of generic vancomycin.

PMID: 19698745 [PubMed - indexed for MEDLINE]

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[+](#) LinkOut - more resources

PLoS One. 2010 May 20;5(5):e10744.

Determination of therapeutic equivalence of generic products of gentamicin in the neutropenic mouse thigh infection model.

Zuluaga AF, Agudelo M, Cardeño JJ, Rodríguez CA, Vesga O.

Department of Pharmacology and Toxicology, University of Antioquia Medical School, Medellín, Colombia.

Abstract

BACKGROUND: Drug regulatory agencies (DRA) support prescription of generic products of intravenous antibiotics assuming therapeutic equivalence from pharmaceutical equivalence. Recent reports of deaths associated with generic heparin and metoprolol have raised concerns about the efficacy and safety of DRA-approved drugs.

METHODOLOGY/PRINCIPAL FINDINGS: To challenge the assumption that pharmaceutical equivalence predicts therapeutic equivalence, we determined in vitro and in vivo the efficacy of the innovator product and 20 pharmaceutically equivalent generics of gentamicin. The data showed that, while only 1 generic product failed in vitro (MIC = 45.3 vs. 0.7 mg/L, $P < 0.05$), 10 products (including gentamicin reference powder) failed in vivo against *E. coli* due to significantly inferior efficacy (E_{max}) = 4.81 to 5.32 vs. 5.99 log(10) CFU/g, $P \leq 0.043$). Although the design lacked power to detect differences in survival after thigh infection with *P. aeruginosa*, dissemination to vital organs was significantly higher in animals treated with generic gentamicin despite 4 days of maximally effective treatment.

CONCLUSION: Pharmaceutical equivalence does not predict therapeutic equivalence of generic gentamicin. Stricter criteria based on solid experimental evidence should be required before approval for human use.

Investigación original / Original research

Definición de medicamento genérico ¿un fin o un medio? Análisis de la regulación en 14 países de la Región de las Américas

Claudia Patricia Vacca González,¹ James F. Fitzgerald² y Jorge A. Z. Bermúdez³

Forma de citar: Vacca González CP, Fitzgerald JF, Bermúdez JAZ. Definición de medicamento genérico ¿un fin o un medio? Análisis de la regulación en 14 países de la Región de las Américas. *Rev Panam Salud Pública* 2005;20(5):214-22.

RESUMEN

Objetivos. Caracterizar la situación y las tendencias regulatorias relacionadas con los medicamentos genéricos en 14 países de América Latina y el Caribe.

Métodos. Entre julio de 2006 y abril de 2007 se recolectó la información sobre las regulaciones y políticas nacionales que afectan o afectan la definición de medicamento genérico y de los servicios asociados en 14 países de América Latina y el Caribe (Argentina, Barbados, Bolivia, Brasil, Colombia, Costa Rica, Ecuador, Guatemala, México, Nicaragua, Panamá, Paraguay, Perú y Venezuela). Además, se recolectó información sobre los incentivos para registrar y producir medicamentos genéricos, la promoción del uso de la denominación común internacional (DCI), la regulación de los estudios de bioequivalencia y la sustitución de los medicamentos prescritos por alternativas de menor costo al público.

Resultados. Se observaron tres tendencias regulatorias: los países que favorecen la fabricación de medicamentos genéricos, la promoción extensiva del uso de la DCI y no ponen restricciones a la sustitución de medicamentos innovadores por genéricos (Argentina, Colombia, Costa Rica, Ecuador y Paraguay); los que cuentan con un esquema orientado a la denominación de la equivalencia terapéutica, es decir, los países restringen la sustitución de los medicamentos originales mediante una lista de medicamentos genéricos autorizados que deben prescribirse bajo su DCI y tener rúbricas distintas (Brasil, México, Panamá y Venezuela); y los que se encuentran en una etapa temprana de su proceso de regulación (Barbados, Bolivia, Guatemala, Nicaragua y Perú). Esta variedad ocasiona dificultades en la caracterización de los mercados farmacéuticos y puede generar segmentaciones ficticias.

Conclusiones. Las esfuerzos de armonización deberán tener en cuenta la compleja situación entre las definiciones adoptadas por los países, el desarrollo de los mercados farmacéuticos nacionales y sus políticas de estímulo a la competencia.

Palabras clave

Denominaciones comunes internacionales para las sustancias farmacéuticas, medicamentos genéricos, control de medicamentos y narcóticos, Américas.

¹ Instituto Nacional de Vigilancia de Medicamentos y Alimentos, Universidad Nacional de Colombia, Sede Medellín, Colombia. La correspondencia se debe dirigir a Claudia P. Vacca, GCM 4 No. 27-85, Apdo. 118, Paraisópolis de Tizón II, Santa Fe de Bogotá, Colombia. Correo electrónico: cpvacca@univision.com.co

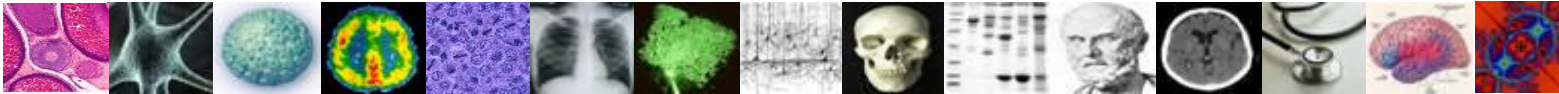
² Unidad de Medicamentos Esenciales, Vietnam y Organización de Salud, Organización Panamericana de la Salud, Ginebra, Suiza.

³ Unidad de Medicamentos Esenciales, Vietnam y Organización de Salud, Organización Panamericana de la Salud, Washington, D.C., Estados Unidos de América.

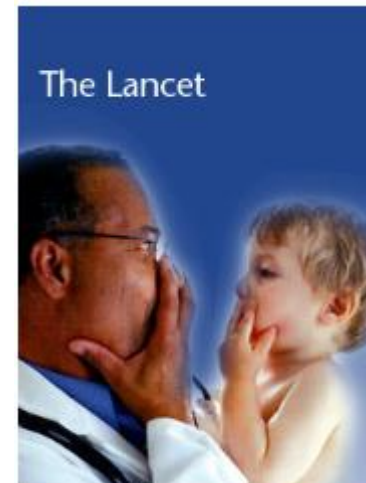
Las recomendaciones internacionales en políticas farmacéuticas establecen la necesidad de promover la competencia en la oferta de medicamentos como una importante estrategia para

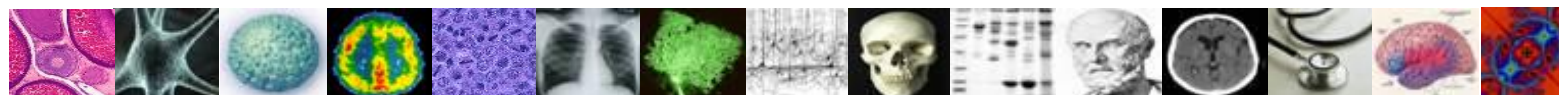
Las recomendaciones internacionales en políticas farmacéuticas establecen la necesidad de promover la competencia en la oferta de medicamentos como una importante estrategia para mejorar el acceso a los mismos. Esto tiene un efecto benéfico sobre los precios y sobre el desarrollo de capacidades nacionales de producción, en especial de medicamentos esenciales (1-3).

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- Aunque no muy numerosa la investigación en medicamentos genéricos viene en aumento
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- Colombia tiene alguna participación
- Hay mucho espacio para desarrollo