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Guidelines for new preventive treatments available for HIV

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Available evidence indicates HIV-infected population promising new approach has emerged. HIV causes an infectious disease that, with the right prevention interventions delivered within a human rights framework, can be controlled and possibly even eliminated. WHO, UNAIDS and the United Nations General Assembly have called for 15 million people to be on ART by 2015. Anti Retroviral Treatment (ART) has considerable benefit, both as treatment and in preventing HIV. Pre-exposure prophylaxis (PrEP) is available from studies with two groups: men and transgender women who have sex with men; and serodiscordant heterosexual couples. Several human clinical trials evaluating the efficacy of daily regimens of the HIV reverse-transcriptase (RT) inhibitors tenofovir disoproxil fumarate (TDF) or Truvada (TDF and emtricitabine [FTC]) are under way among high-risk populations. The results of one trial among men who have sex with men showed that daily Truvada was safe and effective, providing the first support for oral PrEP as a prevention strategy. This article summarizes Guidance on pre-exposure oral prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV.

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Role of hatch-waxman in FDA approval process

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The Drug Price Competition and Patent Term Restoration Act, informally known as the "Hatch-Waxman Act" is a 1984 United States federal law which established the modern system of generic drugs. The informal name comes from the Act's two sponsors, Henry Waxman of California and Senator Orrin Hatch of Utah.

The public health is served by minimizing delay, and a major cause of delay is regulatory uncertainty.Uncertanity in the clinical development requirements, the approval process, patent protection, data protection, and the process of patent infringement dispute resolution can delay or, sometimes, cease new product innovation. The Hatch- Waxman Act can address these uncertainties for both pioneer and generic manufacturers.

Hatch-Waxman amended the Federal Food, Drug, and Cosmetic Act. Section 505(j) 21 U.S.C. 355(j) sets forth the process by which marketers of generic drugs can file Abbreviated New Drug Applications (ANDAs) to seek FDA approval of the generic. Section 505(j)(2)(A)(vii)(IV), the so called Paragraph IV, allows 180 day exclusivity to companies that are the "first-to-file" an ANDA against holders of patents for branded counterparts.

It protects the patent rights of the research-based drug company (pioneer) by adding up to five years of exclusivity onto its patent term. Furthermore, the Act allows the generic to seek market entry prior to expiration of the pioneer's patent term by challenging the patent as invalid or not infringed by its generic product. Once the generic makes that challenge, the pioneer has the ability to sue the generic to contest that claim and prevent the generic's early market entry.

Biography

Rajendar.M is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. He has completed his B Pharm from JSS College of Pharmacy, Mysore during the year 2011. Presently he is pursuing M Pharm in Industrial pharmacy in JSS College of Pharmacy, Mysore. He has attended various National and International Conferences. His current areas of interest are Quality Assurance, Regulatory Affairs, Quality Management Systems, pharmaceutical technology and analytical method development.

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