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Mexico: Lessons learned from the "external review process" and the "recognition schemes" on the reduction of timelines for the approval of marketing authorizations

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The emerging markets represent an important opportunity to the health care industry for both the access to an increasing population and the benefits of countries that are growing on a rate above the developed countries. As part of this group of counties, Brazil and Mexico concentrate the interest of the Health Care companies in Latin America but face an important regulatory problem, the long review times before granting a MA approval and the existence of country specific requirements that differ from the core dossiers develop for EU and US. During this review the actions being taken by the Mexican Government in order to reduce the review and approval timelines by the creation of an "External review" process and the implementation of "recognition schemes" are analyzed. Representatives from both the industry and external reviewers will share their experience and expectations and an assessment of the opportunities of this scheme and the learnings to be shared would be discussed.

Biography

Antonio Trejo Diaz is a Regional Director Regulatory Affairs - Latin America Pharmaceuticals (Gx & Specialty) at Teva Pharmaceuticals, Mexico.

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