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An appraisal of accelerated evaluation processes in the South African context

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Would purpose-specific accelerated evaluation processes, e.g., breakthrough designation, promote registration of essential medicines in South Africa or lead to "forced entry" onto the Fast Track? Regulatory Authorities, the world over employ divergent processes to identify eligible medicines and earmark it for accelerated evaluation. The recent success of the United States Food and Drug Administration's breakthrough designation initiative inspired a similar scheme by the European Medicines Agency and suggests the significance of purpose-specific accelerated evaluation processes. This discussion will explore the South African landscape in respect of accelerated evaluation processes, infer the value of purpose-specific accelerated evaluation processes, and propose how a utilitarian application thereof could broaden access to treatment.

Biography

Michael du Plooy is a registered Pharmacist, Pharmacologist and an admitted Attorney. He is currently employed at Forrester Pharma as a Business Executive tasked with business development, regulatory affairs and group legal responsibilities. His research was awarded the Best Publication in Basic Pharmacology for 2012 in South Africa. He has held various positions in research, pharmaceutical and legal organizations.

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