Registering drugs once could halve cost of medication

The International Generic Drug Regulators Pilot (IGDRP) is promoting the movement to permit pharmaceutical companies to register a product only once in the country of their choice, in order to market it elsewhere in the world. It could drastically improve access to more affordable quality generic medicines and in some cases even halve the selling price.

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Paul Anley, CEO of leading local generics firm, Pharma Dynamics, says that currently pharmaceutical manufacturers and suppliers have to apply and register a product in every country they wish to market the product in, which ends up costing the global pharma industry billions annually.

"Apart from the financial wastage with regards to the duplication of resources, the current system also delays market penetration of essential generic drugs. With the globalisation of the pharmaceutical industry, there should no longer be a need for registrations in every jurisdiction. We have always called for South Africa to recognise a number of developed world regulatory agencies and to have an abridged regulatory system for products registered in Europe and the US for example."

Growing pressures facing generic drug review programmes worldwide resulting from ever increasing numbers of marketing applications, the complexity of products and challenges associated with globalisation, all contributed to the call for reform.

Anley says the benefits of such a proposal would lead to faster approval and the greater availability of generics; more efficient use of resources through mutual reliance and work sharing; a strengthened review process and international regulatory oversight, whilst reducing the regulatory burden. It would also promote a more rapid exchange of safety and quality information on marketed products and will enhance the development of human resources.

"At the same time, access to affordable, quality generic medicine is increasingly important in containing healthcare costs worldwide. Should the proposal be accepted, it could see savings of anything between 10% and 50% across a spectrum of generic products, which is good news for consumers.

Successful model

"Given the success of existing models, such as the WHO's Prequalification of Medicines Programme, which follows an abridged regulatory procedure for expanding access to priority essential medicines, the increasing prevalence of multi-national generic companies and that common quality requirements and CTD formats are already provided by the International Conference on Harmonisation (ICH) guidelines, it makes for a compelling business case."

He cites that among the challenges have been the use of local reference products; various factors influencing business marketing decisions to file the same product applications simultaneously in multiple jurisdictions, including in IPR and data protection; and a reluctance to commit to change in corporate culture on part of both regulatory bodies and multi-national generic companies.

Despite the stumbling blocks, the IGDRP has already received strong support for the concept from Australia, New Zealand, Brazil, Canada, the EU, Korea, Singapore, Taiwan, Switzerland, the US and South Africa. Feedback from other country surveys conducted among regulators and industry have reflected the same positive sentiment for such an approach.

A three-year pilot, launched in 2012, is currently underway and involves work-sharing efforts in the areas of evaluating Active Substance Master Files (ASMF)/Drug Master Files and conditions associated with granting bio waivers. It also includes developing a new approach for referencing products, which all points to a definite and encouraging shift-change in the international generic drug business and regulatory model.