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Challenges of developing generics substitution policies in low- and middle-income countries (LMICs)

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There are few challenges to developing effective generics substitution policies in low- and middle-income countries (LMICs). These include the absence of generics substitution policies, lack of enforcement, lack of evidenced-based data about bioequivalence and lack of acceptance by physicians and patients.

Keywords: Generic medicine, generics substitution, low- and middle-income countries (LMICs)

Generics substitution is an act of switching from a brand innovator medicine to an equivalent, i.e. same active ingredient, dosage, form; generic drug product for the drug product prescribed [1-3]. Generics substitution can be implemented on either a voluntary or a mandatory basis. Generics substitution has been implemented in many European countries as part of demand-side policies to improve the utilization of generics [4]. In fact, mandatory generics substitution has resulted in medicine price reductions of 10–15% [4]. However, this is not a common scenario in low- and middle-income countries (LMICs).

Absence of a generics substitution policy in LMICs is a challenge to promoting the use of generics [5]. Some countries do not have a generics policy or have not positioned their generics policy as an integral part of their medicines policy [6]. Examples of such countries include Malaysia, Thailand and Vietnam [6, 7]. In addition, lack of clarity in legal regulations might prevent effective generics substitution [5]. For example, Malaysia had formulated a generics substitution policy as part of its National Medicines Policy in 2007. However, to date, there is still a lack of implementation and enforcement through legislation [8].

Another major challenge for substitution of generics in LMICs is the lack of evidence-based data/guidelines about bioequivalent or interchangeable medicines. Bioequivalence forms the basis of generics substitution [2]. In fact, concerns about bioequivalence and interchangeability of generics were the main factors affecting healthcare stakeholders', i.e., physicians, pharmacists and patients, attitudes towards generics substitution [4]. Therefore, evidenced-based guidelines could be useful to assist healthcare professionals to appropriately perform generics substitution. Examples of such guidelines are the Orange Book in the US, the British National Formulary (BNF) in the UK, the Schedule of Pharmaceutical Benefits in Australia, and the list of interchangeable medicines in Finland and Sweden [7].

A functioning and reliable medicines regulatory authority is also important in ensuring the quality of generics [5]. Formulation or implementation of generics substitution policy in LMICs will be difficult unless stakeholders believe generic medicines are quality medicines [5]. Therefore, communication between medicines regulatory authorities in LMICs and healthcare professionals and medicine consumers is important to increase awareness of

generics regulatory approval requirements and improve confidence in generics [7].

In addition, the characteristics of generics substitution policies can differ from country to country. In some countries, physicians may oppose, i.e. the level of justification for opposition varies across countries, and patients may refuse generics substitution or both scenarios may occur [4]. Therefore, adequate knowledge and positive perceptions among physicians and patients towards generics substitution is a prerequisite for developing effective generics substitution policies in LMICs. However, the literature shows that misconceptions still exist among these two important healthcare stakeholder groups [9, 10]. Therefore, educational interventions targeted to improve healthcare stakeholders' knowledge about generics are needed.

In conclusion, the many challenges to developing effective generics substitution policies in LMICs include the absence of generics substitution policies, lack of enforcement, lack of evidence-based data about bioequivalence and lack of acceptance by physicians and patients. Adequate focus should be given to formulation/implementation of existing generics substitution policies in LMICs that includes the provision of adequate bioequivalence data that improves healthcare stakeholders' confidence and acceptance of generics.

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