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Strategies for pricing of pharmaceuticals and generics in developing countries

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Dr Brian Godman and Professor Mohamed Azmi Hassali review Rida et al. regarding pricing strategies for pharmaceuticals in developing countries.

Keywords: Developing countries, generics, pharmaceutical pricing policy

Rida and Ibrahim are to be congratulated on their extensive review of ongoing pricing strategies in developing countries [1], also referred to as lower- and middle-income countries (LMICs). These include advocating policies regarding markups for pharmaceuticals, pricing formulae for medicines, external reference pricing, as well as encouraging greater use of generics [2-4]. However, there are concerns over external reference pricing (ERP), especially for new medicines where pharmaceutical companies are potentially delaying launch or not launching in some countries to maintain high prices [5]. There are also concerns over the ability to rapidly obtain low prices for generics if prices under ERP systems are only reviewed annually or biannually. Aggressive pricing policies in The Netherlands, including quarterly tendering, led to prices of generic omeprazole and simvastatin dropping to just 2% of the originator price in a short time period [6]. In Sweden, compulsory generics substitution with the lowest priced generic drug also led to rapid price erosion following generic availability. Prices fell further following the instigation of monthly auctions where the cheapest generic drug was guaranteed a substantial proportion of the market the following month [7, 8].

The prices of pharmaceuticals are a particular issue in LMICs, where medicines can account for up to 60% of total healthcare expenditures, and where up to 90% of the population purchase medicines through co-payments [9, 10]. High co-payments impact on adherence of non-communicable diseases (NCDs) as well as on access to

biologicals to treat immunological diseases [11-13]. This is a concern with NCDs as for example, currently three out of four patients with hypertension live in LMICs [14]. As mentioned by Rida and Ibrahim, promoting generics is a major way to reduce prices and enhance access to appropriate medicines [1, 10, 15, 16]. Although things are changing [10, 16], to date, there have only been a limited number of policy evaluations surrounding generics in LMICs [17]. There is also a comparative lack of strategies in place to combat the activities of pharmaceutical companies who are promoting their branded medicines negatively impacting on the use of generics [18]. The lack of promotion of generics can often be coupled with a lack of formal pricing strategies for generics [8]. This can be a major concern for countries and patients with NCDs, as generics for NCDs can be manufactured and distributed for as little as US\$1 per patient per month [19, 20].

The lack of formal pricing strategies in place for generics in LMICs contrasts sharply with European countries where there are multiple formal pricing policies. These can be collated under three main themes [10, 21, 22] and include [8]: *regulated systems* (prescriptive pricing) where there are established rules for the pricing of generics, as seen in Belgium, Croatia, France, Hungary, Norway and Poland; *free pricing* – where manufacturers are (relatively) free to set prices of generics, as seen in Germany, The Netherlands, Sweden and the UK; however, typically there are programmes in place to obtain low prices; or a *mixed approach* – which is a combination of the two different approaches, as currently seen in Austria [10, 23-26].

As a result of the different pricing policies, there can be substantial price differences for generics [8, 22, 27]. Overall, generics prices can vary by up to 36 fold across countries depending on the pricing policies [28], with prices generally lower in countries with higher consumption of generics [29]. This is independent of the size of the country [30, 31]. Different countries across Europe and other parts of the world have also used a variety of other approaches to promote the use of generics. These include educational approaches, financial incentives and laws. Laws include compulsory generics substitution, as seen in Sweden, or compulsory International Nonproprietary Name (INN) prescribing, as seen in Lithuania [7, 30].

Despite the efforts being made, there are still a number of barriers that need to be addressed to enhance the prescribing and dispensing of generics, especially in LMICs [10, 32, 33]. These include addressing fears associated with generics substitution that are enhanced by concerns over the efficacy and safety of generics [34, 35]. Such fears resulted in Hassali et al. developing a list of requirements that should be met to enhance successful substitution [36]. Educational needs include encouraging high INN prescribing which is advocated by the World Health Organization (WHO) for non-controversial products, as seen in Scotland where rates are close to the 100% [8, 37]. Financial incentives include greater patient co-payments for branded products of the same molecule, which is typically practised across Europe [22]. Potential initiatives can also include reducing financial disincentives to the prescribing of generics, as currently seen in China. Here, both hospitals and physicians need to prescribe branded products with associated procured discounts to enhance their incomes [38]. This is in addition to the measures mentioned in Table 1 by Rida and Ibrahim [1].

It is important that appropriate care is taken when introducing pricing policies for generics. In 2012, the South Korean Government set the same maximum reimbursement price for originators and generics in an attempt to make the market more competitive [39], building on earlier reforms mentioned in Table 1 by Rida and Ibrahim [1]. However, given the concerns that still

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exist among physicians in Korea regarding generics, the opposite was achieved. The price dispersion between different generics significantly decreased and originator utilization significantly increased [39]. A similar situation was seen when compulsory INN prescribing was introduced in Abu Dhabi, United Arab Emirates. Implementation of this policy did not achieve the desired results as physicians were not incentivized to preferentially prescribe the generic medicines and pharmacists' remuneration was not altered to preferentially dispense the cheapest INN product [40].

Many countries have also implemented a variety of approaches to the pricing and reimbursement of new medicines. Whilst all countries use critical appraisal techniques to assess the level of health gain with new medicines as part of pricing negotiations, some countries use this as a basis for pricing negotiations, e.g. Austria, France and Germany. Others use this information to develop economic parameters, such as the extent of an increase in quality adjusted life years (QALYs) with the new medicine with or without a budget impact analysis [41–43]. One concern is that most countries that utilize QALYs do not set thresholds, which can be exploited by pharmaceutical companies, especially in emotive disease areas, such as cancer and orphan diseases [41, 44, 45].

There is also growing use of risk-sharing arrangements brought about by the ever-increasing prices of new medicines and issues of affordability in European countries [42, 46, 47]. This contrasts sharply with LMIC countries where there are currently few formal pricing approaches for new medicines, as discussed by Rida and Ibrahim [1]. Examples of pricing strategies that could be considered by LMICs when funding new medicines include those currently instigated in Austria [42, 48]. This is in addition to ERP as advocated by WHO [4]. In Austria, new medicines that are similar to existing standards are expected to be priced lower than the current standard prices for reimbursement [49]. New medicines that have added benefit can potentially command up to 10% more than the current standard prices, with prices for new medicines that are deemed to have substantially more added value, being allowed to have prices similar to European countries endorsed by health economic evaluations [49]. In the case of LMICs, this would mean prices similar

to other LMICs with similar economic situations, as seen in Europe [3]. With only a few new medicines typically seen as innovative, this means that most new medicines will be priced below or just above current standards [42, 48], greatly increasing affordability and access.

In conclusion, Rida and Ibrahim's research has been extensive. They have highlighted the need for LMICs to develop suitable pricing strategies for medicines to enhance access to affordable medicines. This is essential given rising rates of NCDs and other diseases. There is an opportunity for LMICs to learn from other countries, such as those in Europe who are developing strategies to cope with growing resource pressures on healthcare systems and the need to maintain equitable and comprehensive health care for all [8, 42].

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