Contents

Editorial

Reducing neonatal mortality: a need to address pre-term births
Neena Raina, Rajesh Mehta.............................................................................................................................................................. 1

Perspective

Spiritual health, the fourth dimension: a public health perspective
Neera Dhar, S. K. Chaturvedi, Deoki Nandan........................................................................................................................................... 3

Review

Influencing factors for household water quality improvement in reducing diarrhoea in resource-limited areas
Thant Zin, Kamarudin D. Mudin, Than Myint, Daw K. S. Naing, Tracy Sein, Shamsul B. S. ................................................................. 6

Stigma related to HIV and AIDS as a barrier to accessing health care in Thailand: a review of recent literature
Sian Churcher ......................................................................................................................................................................................... 12

Changing epidemiology of dengue in South-East Asia
Rajesh Bhatia, Aditya P Dash, Temmy Sunyoto ................................................................................................................................. 23

Original Research

Promoting tobacco cessation by integrating ‘brief advice’ in tuberculosis control programme
Jagdish Kaur, Kuldeep S. Sachdeva, Bhavesh Modi, Dinesh C. Jain, Lakhbir S. Chauhan, Paresh Dave, Rana J. Singh, Nevin Wilson................................................................. 28

Annual risk of tuberculosis infection in Sri Lanka: a low prevalent country with a high BCG vaccination coverage in the South-East Asia Region
Pushpa Ranjan Wijesinghe, Paba Palihawadana, Sunil De Alwis, Sudath Samaraweera ......................................................................... 34

Threat of HIV/AIDS in children: social, education and health consequences among HIV orphans and vulnerable children in Myanmar
Myo-Myo-Mon, Saw-Saw, Yin-Thanh-Nu-Oo, Khin-Ohnmar-San, Wai-Wai-Myint, SanSan-Aye, Pyone-Thuzar-Nge......................................................... 41

Development of birth weight for gestational age charts in a Sri Lankan setting – methodological issues
T. Ruwanpathirana, Dulitha N. Fernando, Hemanta Senanayake .............................................................................................................. 47

Assessing compliance to smoke-free legislation: results of a sub-national survey in Himachal Pradesh, India
Ravinder Kumar, Gopal Chauhan, Srinath Satyanarayana, Pranay Lal, Rana J. Singh, Nevin C. Wilson ............................................................................. 52
Growth parameters at birth of babies born in Gampaha district, Sri Lanka and factors influencing them
Priyantha J. Perera, Nayomi Ranathunga, Meranthi P. Fernando, Tania D. Warnakulasuriya, Rajitha A. Wickremasinghe ....... 57

Report from the Field

Integration of leprosy services into the General Health Service in Sri Lanka: overcoming challenges to implementation in a remote district
Thushanthi S. Wijesinghe, Pushpa Ranjan Wijesinghe ................................................................. 63

Legislation an essential tool for ensuring access to medicines policy goals
Michele Forzley, Jane Robertson, Anthony Smith .............................................................. 69

Generic medicines policies in the Asia Pacific region: ways forward
Tuan A. Nguyen, Mohamed A. A. Hassali, Andrew McLachlan .................................................. 72

Recent WHO Publications

Birth defects in South-East Asia: a public health challenge: Situation analysis .................. 75
Tuberculosis control in South-East Asia Region: Annual TB report 2013 ............................. 75

Guidelines for Contributors ........................................................................................................... 77
Generic medicines policies in the Asia Pacific region: ways forward

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ABSTRACT

Generic medicines are a key strategy used by governments and third-party payers to contain medicines costs and improve the access to essential medicines. This strategy represents an important opportunity provided by the global intellectual property regimes to discover and develop copies of original products marketed by innovator companies once the patent protection term is over. While there is an extensive experience regarding generic medicines policies in developed countries, this evidence may not translate to developing countries. The generic medicines policies workshop at the Asia Pacific Conference on National Medicines Policies 2012 provided an important opportunity to discuss and document country-specific initiatives for improving access to and the rational of use of generic medicines in the Asia Pacific region. Based on the identified barriers and enablers to implementation of generic medicines policies in the region, a set of future action plans and recommendations has been made.

Key words: Access to medicines, developing countries, essential medicines, rational use

INTRODUCTION

The World Health Organization (WHO) began to develop practical guides for member states in formulating national medicines policies in 1975. The guidelines were first published in 1988 and then updated in 2001. The WHO recommended individual countries to develop their own locally appropriate national medicines policy, primarily focused on improved access to, quality and rational use of medicines.

Access to medicines continues to be one of the biggest challenges confronting the global political agenda.¹ Despite some progress made, one-third of the world’s population continues to lack a regular access to essential medicines, with the figure increasing to 50% in the poorest countries of Africa and Asia.² This long-standing WHO intuitive estimate has been supported by results of recent household surveys and the study by Cameron et al.,³ which is the first exact measurement of access to medicines in developing and middle-income countries.² The United Nation’s Millennium Development Goal 8E acknowledges the need to provide access to affordable essential medicines in developing countries.⁴

Lack of access to essential medicines in developing countries relates to two classes of medicines.⁵ The first is a lack of access to new (patented) medicines as a result of the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement, which restricts access to newer essential medicines due to higher costs. It can also arise because of absence of medicines, as there are insufficient commercial incentives for the global pharmaceutical industry to develop new medicines to treat diseases associated with poverty, given the market-driven nature of the industry. The second is a lack of access to existing medicines because of patients’ inability to pay for them. This reason is deemed ‘the most frequently cited cause of inadequate access to medicines’ in developing countries.⁵ Often, all the three reasons are responsible.

Usually, generic medicines with proven safety and efficacy represent a key strategy used by governments and third-party payers to contain cost of healthcare and
improve access to existing medicines. This strategy is promising considering the impending expiry of patents of many ‘blockbuster’ medicines. However, while there is an extensive experience from developed countries with regard to pro-generic medicines policies, empirical studies in developing countries are lacking. [6] This makes it especially difficult for developing countries to decide on a course of action. In the generic medicines policies workshop at the Asia Pacific Conference on National Medicines Policies, [7] country-specific initiatives for improving access to and rational use of generic medicines in Asia Pacific region were discussed and documented. Key barriers and enablers to development and implementation of generic medicines policies were identified and steps to address barriers and enablers were proposed.

COUNTRY EXPERIENCES AND LESSONS LEARNED

Workshop participants indicated that many countries in Asia Pacific region did not officially have a generic medicines policy or position their generic medicines policy as an integral part of their National Medicines Policy. Few regional countries have comprehensively implemented generic medicines policies with strong regulatory requirements (i.e. statutory provisions and regulations to expedite generic entry, permit generic substitution and/or mandate generic prescribing policies) in combination with incentives for the development of the generic markets, acceptance and rational generic medicine use. For example, Vietnam adopted a National Medicine Policy in 1996, but there were no generic medicines policies embedded. It was not until 2009 that an Aide Memoire on Strategic Collaboration in Pharmaceuticals was signed by WHO and the Ministry of Health of Vietnam, which mentioned a strategy to develop and promulgate a national generic medicines policy to ensure affordability of safe and quality medicines. [8] Another example came from Malaysia, whose 2007 National Medicines Policy contained a generic medicines policy, although some of its key components have not been implemented. [9]

Key barriers

A number of barriers to the development and implementation of a comprehensive generic medicines policy was documented in the workshop. The first is the mistrust in the pharmaceutical quality of available generic medicine products in some countries in terms of safety and efficacy. The lack of clear bioequivalence assessment systems as a regulatory requirement in generic medicines registration or lack of appropriately skilled inspectors and monitoring to ensure the quality of generic medicine products was reportedly attributable to this mistrust. Even in some countries where bioequivalence was assessed, the mistrust still existed because of the lack of effective communication from regulators to make clear statements about the procedures involved in approving generic medicines. References came from several countries, including those in Pacific Islands.

The mistrust related to the pharmaceutical quality of generic medicine partly results in a poor acceptance of generic medicines by consumers and health professionals. Lack of knowledge of generic medicines and misconceptions that discount price equates to ‘discount’ quality also contributed to this poor acceptance. In addition, widespread unethical promotional incentives for prescribers from some pharmaceutical companies were reported to influence physician prescribing behaviour, leading to recommendation of more expensive branded generics. Meanwhile, only few regional countries have included financial incentives to physicians and pharmacists in their generic medicines policies to promote prescribing and dispensing of generic medicines.

These barriers were believed to render weak generic markets and low uptake of generic medicines, although generic substitution and/or generic prescribing have also been reported in many regional countries. The failure to fully implement generic substitution policies and guidelines also contributed to this resulting low uptake. However, the increase in generic medicines uptake does not automatically translate to savings or improvement in affordable access if pricing policies fail to ensure low prices of generic medicines. This was witnessed from several regional countries, where generic prices were only slightly lower than the originator brand prices (e.g., in Australia) or in some cases even higher (e.g., in Malaysia).

Key enablers

Facing these barriers, Asia Pacific regional countries have undertaken various initiatives for improving access to and use of generic medicines. These initiatives can be classified into ‘four Cs’ enabler groups. The first is to co-ordinate the implementation of generic medicines policies including procurement, re-imbursement, retail price controls, reference pricing and alignment of financial incentives among prescribers, dispensers and consumers to support the uptake of low-priced generic medicines. The second is commitment to procedures and infrastructure to demonstrate, evaluate and promote bioequivalence and maintain product quality to build confidence in generic medicines. The third is communication from regulators about the procedures involved in approving generic medicines to promote trust in generics quality to the community. Finally, community trust must be obtained through education to public/consumers and health professionals to support understanding and confidence in generic medicine products and allow informed choices by consumers. These ‘four Cs’ are interconnected and must be achieved simultaneously if the generic medicine policies are to be successful.
BUILDING EFFECTIVE COMPETITIVE MARKETS FOR GENERIC MEDICINES

A principal assumption in generic medicine policies is that generics are significantly less expensive than their originator medicine counterparts. This is because, on the one hand, generic manufacturers do not incur the cost of medicine discovery and are thus able to maintain profitability at a lower price. On the other hand, they face increasing competition as the medicines are no longer protected by patents, resulting in increase in the number of manufacturers/suppliers. However, effective, efficient competition will not arise from a completely unregulated pharmaceuticals market. Core regulations including general laws (e.g. criminal law, contract law, competition law and anti-corruption law) and pharmaceutical sector regulation must be in place and adequately enforced to create competitive markets for generic medicines.[10]

WAYS FORWARD

Given the complex, varied and interdependent factors influencing the success of generic medicines policies, Asia Pacific regional countries need to integrate their generic medicines policies within the broader framework of national medicines policies and make active efforts to promote confidence in their quality and use. The national medicine regulatory agency needs to be strengthened with a capacity to assure the quality of generic medicines. A robust and functioning medicine regulatory system will assure the actual quality of generic medicines, but the perceived low quality of generic medicines must also be addressed. This can be achieved through effective communication from regulators regarding requirement for generic medicines registration, in combination with educational campaigns to public and health professionals. Other effective initiatives include publishing details of Good Manufacture Practice inspections as per the WHO Prequalification Programme or publishing test results as does the Global Fund.

When the scepticism of and uncertainty about the quality of generic medicines has been successfully addressed, supportive regulations providing for substitution of generic medicines are necessary. Of equal importance is the availability of policies that align pro-generic medicine incentives for prescribers, dispensers and patients to increase generic medicines uptake. Pricing and purchasing policies such as reference pricing and tendering may also be needed to ensure low prices of generic medicines. For sustainability of effective generic medicines policies, the progress in implementation of these policies needs to be monitored. It includes regular reporting on quality monitoring, prices and use of generic medicines, as well as assessment of changes in consumer and healthcare professional attitudes to generic medicine products.

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