



GenMed 010: a one day workshop on generic medicines

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BRIEF REPORT

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Abstract

This report outlines the content of a one-day workshop on Generic Medicines that was held at KIST Medical College, Lalitpur, Nepal on 13th December 2010, which was attended by 32 delegates from different institutions in Nepal, including pharmacists, pharmacologists and medical doctors. Right medicine, right patient, right dose, right frequency and duration, right information and right monitoring are conditions to be fulfilled for the rational use of medicine (RUM). The World Health Organization (WHO) defines generic medicine as 'a pharmaceutical product, usually intended to be interchangeable with the innovator product, marketed after the expiry of patent or other exclusivity rights'. Economic factors, supportive legislation and regulation, public and professional acceptance and quality assurance are key enabling factors promoting use of generics. Increased patent protection for medicines and removing process patents is a key feature of new trade agreements and newer medicines for diseases like HIV/AIDS, tuberculosis and infectious diseases are likely to be more expensive. The Medicine and Therapeutics Committee (MTC) can play a key role in promoting generic medicine use in institutions.

Nepal being among the Least Developed Countries (LDCs) need not provide patent protection for medicines until 31st December 2015. Only a few 'true' generics are available in Nepal and there is huge cost variation in the price of different branded generics. Clinicians have concerns about the quality of medicines in general, substitution of poor quality brands by pharmacists and about therapeutic substitution. Generics have to meet the same regulatory requirements and be bioequivalent to reference preparations assuring their quality.

Key Words

Generic medicines, Nepal, Patents, Rational use of medicines

This report outlines the content of a one-day workshop on Generic Medicines that was held at KIST Medical College, Lalitpur, Nepal on 13th December 2010, which was attended by 32 delegates from different institutions in Nepal. Nepal is a developing country in South Asia located between China and India. In 2006 the population was 25.6 million.¹ There are 17 medical schools in Nepal producing more than 1000 doctors annually.² The country spends 5.3% of gross domestic product on health and has 0.08 health centres per 100,000 population and 2 doctors of modern medicine per 10,000 population.¹ In 2006, for every 10,000 population there were 2 nurses, 0.1 pharmacists and 6.3 community health workers.

There are three Universities offering Masters and PharmD programs in pharmacy and a number of institutions offering Bachelor level programs. Participants attending the one-day workshop were from Kathmandu University, Kathmandu Model Hospital, B and B Hospital, Kathmandu Medical College, Kathmandu University School of Medical Sciences, CIST College, MedSolutions Consultancy, Patan Academy of Health Sciences, Manmohan Institute of Health Sciences, Sunsari Technical College and KIST Medical College (KISTMC). PharmD students, MPharm students, faculty members, community pharmacists, nurses and medical doctors participated. There were three small groups of 10 or 11 participants each. The workshop employed a mix of facilitator presentations, group work and group presentations to explore the subject. The resource persons from outside KISTMC were Associate Professor Dr. MA Hassali from the Discipline of Social and Administrative Pharmacy, Universiti Sains Malaysia (USM), Mr. BB Thapa, Chief Drug Administrator, Ministry of Health and Population, Government of Nepal and Dr. P Subish from College of Medical Sciences, Bharatpur, Nepal. Dr. Hassali's visit aimed at increasing collaboration and cooperation between USM and Nepalese institutions. Resource persons from KISTMC were Dr. RM Piryani from the Department of Medicine, Dr. N Mishra from Paediatrics and Dr. R Shankar from the Clinical Pharmacology department.

The topics covered in the workshop were: RUM; defining, improving quality of use of, and practical prescribing advice for, generic medicines; information on patents, intellectual property rights (IPR) and access to medicines in developing nations; and Medicine and Therapeutics Committee (MTC)/DTC. The content of individual sessions will now be described.



Rational use of medicines (RUM)

The proceedings started with a brief presentation by Dr. Shankar. RUM is said to occur when patients receive medicines appropriate to their clinical needs, in doses that satisfy their own individual requirements and at the lowest cost to them and their community. Right medicine, right patient, right dose, right frequency and duration, right information and right monitoring are the conditions to be fulfilled. The WHO and the International Network for the Rational Use of Drugs (INRUD) have developed indicators to measure drug use in health facilities. The prescribing indicators, a subset of drug use indicators, measure average number of drugs prescribed, percentage of drugs prescribed by generic name and from an essential drug list or a formulary, and the percentage of encounters with an antibiotic and an injection prescribed. Large number of drugs per prescription (polypharmacy), misuse of antibiotics and injections and overuse of vitamins and tonics are common medicine use problems in Nepal.

What healthcare professionals should know about generics

The second session by Dr. Hassali was on 'Improving the quality use of generic medicines what the healthcare professionals should know'. To recover costs associated with the research and development of medicines, the company developing the brand medicine (innovator company) is granted a period of time known as a patent during which only it can market the medicine. After this period is over other companies can manufacture and sell the medicine, often at a lower price. These medicines are called 'generic medicines' or 'generics'. WHO defines generic medicine as 'a pharmaceutical product, usually intended to be interchangeable with the innovator product, marketed after the expiry of patent or other exclusivity rights'. Economic factors, supportive legislation and regulation, public and professional acceptance and quality assurance are key enabling factors promoting use of generics. Among the economic factors are support by government and private health sectors, retail pricing mechanisms that favour use of generics and reference pricing for reimbursement programs. Among the regulatory measures are those favouring generic prescribing and substitution and the requirement that labels and drug information contain generic names. To be given marketing permission it must be demonstrated that a generic is *bioequivalent* to a reference or standard preparation. Bioequivalence can be defined as the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.

Patents, IPR and access to medicines in developing nations

In his second session Dr. Shankar shared information about patents, Trade Related Intellectual Property Rights (TRIPS) and access to medicines in developing nations. A medicine has been defined as a substance which is used or intended to be used to modify or explore physiological systems or pathological states for the benefit of the recipient. Due to the negative connotations of the term 'drug' with 'drugs of abuse'

the WHO advises use of the term 'medicine' rather than 'drug'. Rational selection of medicines, affordable pricing, sustainable financing and reliable health and supply systems are key factors determining access to medicines. In Nepal because of the difficult topography access to medicines is difficult. The Nepalese primary healthcare system operates at the levels of the sub health post, health post and primary health centre. The country has three main geographical regions – the lowlands of the terai bordering India in the south, the middle hills and the mountains. Roads are only slowly making inroads in the rural areas of the country and many villages and towns are three to four days walk from the nearest road head. Medicines and other commodities are more expensive in areas distant from roads. A system of community drug financing was developed to ensure medicine supply in rural areas. The General Agreement on Tariff and Trade (GATT) and TRIPS resulted from negotiations between nations in the early 1990s. Two types of medicine patents exist. A "process patent" only allows the process of manufacturing of the medicine can be patented. The molecule itself cannot be patented and other companies can manufacture the same molecule using a different manufacturing process. In this case, competition keeps medicine prices low. A "product patent" results in the drug molecule being patented. Increased patent protection for medicines and not allowing process patents are key features of new agreements and newer medicines, especially for diseases such as HIV/AIDS, tuberculosis and infectious diseases, resulting in them being more expensive.

MTC/DTC, generic medicines and RUM

Dr. Piryani, Chairperson, of the MTC, KISTMC shared the importance of the MTC in promoting use of generic medicines and the initiatives of the MTC at KISTMC to promote rational use of medicines. MTC provides a forum to bring together various stakeholders involved in use of medicines. In Nepal MTCs are functioning only in a few hospitals. Many initiatives have been tried at a national level to promote MTCs. The strategies to promote RUM can be divided into educational, managerial and regulatory. Educational strategies aim to inform and persuade prescribers and users, managerial ones structure and guide decisions made by prescribers and patients while regulatory strategies aim to restrict and limit decisions made. In service education programmes, drug information centers, drug newsletters and bulletins and hospital formulary and standard treatment guidelines (STGs) are educational strategies. Among the managerial strategies are implementing STGs, audit and feedback, clinical pharmacy programs, medicine restrictions and avoiding perverse financial incentives. Regulatory strategies include supporting national regulations and a balanced hospital policy on pharmaceutical promotion

Generic medicines and Nepal

Mr. Thapa shared details about the drug registration process in Nepal. Nepal being among a LDC need not provide patent protection according to TRIPS agreement



till 31st December 2015. This offers many opportunities. He also discussed International Non-proprietary names (INN) and recent modifications carried out to ensure the names are uniform all over the world. Participants further explored the issue through group work. In Nepal only a few companies are manufacturing generics and most of the medicines in the market are 'branded generics'. There are also problems in obtaining reference preparations for bioequivalence studies and lack of technical equipment and sites for the same. The number of laboratories and institutions with facilities for measuring drug levels and doing quality assurance studies is low.

Generic medicines available in Nepal and a cost comparison

Dr. Subish in his session through group activities brought out the issue of tremendous cost variation among different brands of the same medicine in Nepal. Most medicines available in the country are branded generics marketed by different companies under their brand names. Generic medicines in Nepal are often not recognized and receive limited focus in the national medicines policy. Examples of 'true' generics available in Nepal are injectable adrenaline, injectable atropine, injectable metronidazole, injectable heparin, liquid paraffin solution, and injectable hydrocortisone among others.

Challenges in prescribing generic medicines – the clinician's perspective

After lunch Dr. Mishra shared concerns of clinicians about generics with the audience. Many clinicians are not aware about 'generics' as opposed to branded generics available in the Nepalese market and had concerns about quality of medicines in general and of generics in particular. Generic substitution is when a, usually lower priced, generic is substituted for a brand prescribed by the prescriber or when a lower-priced brand is substituted for a more expensive one. The term in South Asia can mean substitution either with a generic preparation of the same medicine or with a branded generic, a preparation marketed by a pharmaceutical company under its brand name either after the patent of the innovator company expires or previously by manufacturing the same molecule using a different process or with small modifications in the manufacturing process. Therapeutic substitution is when another medicine from the same therapeutic class is substituted for a prescribed one. An example could be substituting omeprazole for lansoprazole, the substitution should not be made without the consent and awareness of the prescribing doctor. Generic prescribing is a major cost reducing strategy. In Nepal there are insufficient drug testing laboratories and post-marketing surveillance mechanisms. If the doctor prescribes by generic name, pharmacists may substitute a poor quality brand due to perverse financial incentives. There may be problems in bioavailability especially of medicines with a narrow therapeutic index. In Nepal the number of qualified pharmacists is low raising problems about proper dispensing and generic and therapeutic substitution.

There are concerns about drugs with narrow therapeutic index or with drugs with differing bioavailability between different formulations or of biological products. Bigger fear for doctors is unavailability of mechanisms to explore whether

substandard drugs may have contributed to therapeutic failure and lack of protective legislation for doctors in this case.

Quality use of generic medicines: Myths and facts

In their joint session Dr. Azmi and Dr. Subish addressed concerns about generics. Generics have to follow all the registration requirements of innovator brands and are manufactured in units having current good manufacturing practice (cGMP) certification. Dr Azmi also had shared findings from his own survey among general practitioners in Malaysia with relation to generic medicine use. The study which was published in the journal 'Health Policy' early 2010 reported that 33% of the GPs surveyed had doubts about the efficacy of generics and 52.9% thought branded medicines had to meet higher safety standards than generics.³ With respect to consumers, the discussions was centred the common misconceptions reported towards generic and this was extracted from findings of a review article published by Dr Azmi's research group on consumers views towards generic medicine which was published in the 'International Journal of Pharmacy Practice' in the year 2009.⁴ Similarly both Dr Azmi and Dr Subish had pointed out that people also think that expensive medicines are better. Among the myths tackled were generics are cheaper because they are of lower quality and innovator brands work better and have lesser side effects, The final session titled 'Generic medicines – the way forward' was an activity based one. The session concentrated on Nepal in the post-TRIPS era in the year 2020, educating the community about generics and promoting use of generics in a teaching hospital.

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