

Briefing Document

Essential Medicines for Non-Communicable Diseases (NCDs)

The major burden of disease related to NCDs cannot be reduced without equitable access to essential medicines. While primary prevention of NCDs is a key objective, treatment of existing cases (secondary prevention) is also needed and widely expected by patients. Medicines are an essential component of the treatment of cardiovascular diseases, diabetes, chronic obstructive pulmonary disease including asthma, many cancers (including palliative pain treatment) and depression.

In most low- and middle income countries access to essential medicines for the treatment of the most common acute communicable diseases is already inadequate.^{1,2} For example, recent surveys in over 40 countries showed that in the public and private sector, generic medicines for the treatment of acute diseases were only 56.1% and 65.6% available respectively. Ensuring equitable and regular access to essential medicines for chronic disease is proving even more difficult, and here availability was only 36% and 54.7%

Low public sector availability of essential medicines is often caused by a lack of public resources or under-budgeting, inaccurate demand forecasting, and inefficient procurement and distribution. This forces patients into the private sector, where generic medicines are often 2-3 times more expensive.³ Private sector preference for originator brand products further increases the price and makes treatment even more unaffordable. High private sector prices are caused by a high manufacturer's selling prices, taxes and tariffs, and high mark-ups in the supply chain.

Chronic treatment puts an enormous and continuous financial strain on household budgets. In most developing countries, the highest component of household health related expenditure is on medicines. The cost of chronic medicine treatment often constitutes catastrophic health expenditure, pushing the family below the poverty line. In such marginal situations the availability of generic medicines in the public sector proves to be the most cost-effective option. For example, in the Philippines purchasing originator brand atenolol would push an additional 22% of the population below US\$1.25 per day compared to 7% if the lowest priced generic equivalent was bought instead.⁴

Medicine quality is also a problem. For example, a recent survey in Rwanda showed that 20% of hypertensive medicines purchased in the market were of substandard content and 70% were of insufficient stability.⁵ Similar results were found for other essential medicines in many other developing countries. The number of recorded cases of falsified (counterfeit) medicines for chronic diseases is also increasing, for example through unregulated internet sales used by patients on chronic treatment. Finally, challenges remain with the development of evidence-based clinical guidelines for NCDs, including the diagnostic standards and international agreement on when to start medicine treatment. Especially in the area of NCDs the international pharmaceutical industry is heavily engaged, because of the long-term market potential of chronic treatments. For this reason the potential conflicts of interest between the industry, patient organizations, professional associations, health insurance and public sector organizations must be carefully identified and managed. This also applies to low- and middle income countries where many locally produced "branded generics" are aggressively marketed.

Many policy options exist to address these problems and to achieve, for NCDs, the same three main objectives that are valid for any general essential medicines programme: equitable access (rational selection, affordable prices, sustainable financing and reliable systems), assured quality and safety, and quality use by prescribers and consumers. In most countries the national situation will need to be assessed first, to decide which approaches are most relevant to which country. These measures include one or more of the following:

Rational selection of a limited range of essential medicines, and independently developed evidence-based clinical guidelines for prevention and treatment of NCDs. These form the basis of the national programme of supply, reimbursement, quality assurance and quality use of NCD medicines.

Adequate, equitable and sustainable financing, e.g. through national or social health insurance systems that cover essential medicines, and prioritizing the public sector medicine budget by targeting widespread access to a reduced number of essential generic medicines for NCDs.

Affordable prices can be promoted through various policies. These include: improved public procurement (although this is often not a problem); social marketing of generic essential medicines through the private sector; generic policies (including preferential registration procedures, quality assurance of generic products, generic substitution, financial incentives and education of prescribers and consumers); separating the prescribing and dispensing; controlling the wholesale and retail mark-ups through regressive mark-up schemes; and exempting essential medicines from import tax and VAT (which can be classified as a tax on the sick). For patented medicines several other options exist to promote affordability. These include: national clinical guidelines which recommend essential medicines for which generic products are available; therapeutic substitution; reimbursement measures (e.g. reference pricing); differential pricing; local production through voluntary licenses; and the flexibilities of international trade agreements to introduce generics while a patent is in force, such as government use and compulsory licenses for local production or importation.

The **quality and safety of medicines** for NCDs require a functional national regulatory authority which is adequately resourced and staffed, and with legal powers to inspect facilities and products and to enforce the regulations. This also includes regulatory measures to encourage and enforce ethical promotion, and systems of post-marketing surveillance and pharmacovigilance.

The **quality use of medicines** by prescribers and consumers can be promoted by a large number of well-proven interventions, which include: a dedicated national body to monitor and promote quality medicine use; national essential medicines lists and formularies used for supply and training; evidence-based diagnostic and clinical guidelines; drugs and therapeutic committees in all major hospitals and districts; and financial (reimbursement or pricing) incentives.

While all of the above interventions should form part of any general national medicine policy and essential medicines programme, the enormous current and future disease burden in low- and middle income countries warrants a **(temporary) separate and dedicated programme focused on essential medicines for NCDs within the scope of a national medicine policy**. Much experience has already been gained with the long-term treatment of AIDS, and the further improvement of the treatment of the NCDs can be expanded in the future to include essential medicines for less frequent but debilitating chronic diseases such as epilepsy and schizophrenia.

Geneva

April 2011

¹ Mendis S, Fukino K, Cameron A, Laing R, Filipe Jr. A, Khatib O, et al. The availability and affordability of selected essential medicines for chronic diseases in six low- and middle-income countries. *Bull World Health Organ.* 2007;85(4):279-87.

² [Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis](#). A. Cameron, M Ewen, D. Ross-Degnan, D. Ball, R. Laing. *The Lancet*, Early Online Publication, 1 December 2008 doi:10.1016/S0140-6736(08)61762-6

³ WHO The world health report: health systems financing: the path to universal coverage Geneva 2010

⁴ Niëns LM, Cameron A, Van de Poel E, Ewen M, Brouwer WBF, et al. (2010) Quantifying the Impoverishing Effects of Purchasing Medicines: [A Cross-Country Comparison of the Affordability of Medicines in the Developing World](#). *PLoS Med* 7(8): e1000333.doi:10.1371/journal.pmed.1000333

⁵ Twagirumukiza, Marc, Cosijns, An, Pringels, Eveline, Remon, Jean Paul, Vervaeet, Chris, Van Bortel, Luc Influence of Tropical Climate Conditions on the Quality of Antihypertensive Drugs from Rwandan Pharmacies *Am J Trop Med Hyg* 2009 81: 776-781