

Helpdesk Report: Availability of essential medicines

Date: 1 October 2012

Query: What are the key factors that result in low availability of essential medicines in resource poor settings? Which of these are the main barriers for the public and private sectors and why:

- a. National procurement systems including adequate forecasting of volumes and ability to negotiate prices
- b. Quality assessment of priority products
- c. National supply, storage and distribution systems that minimize leakage and other waste
- d. Human resource capacity
- e. Facility level ordering, storage and distribution systems (does this differ by level of facility?)
- f. Other factors

How can the key factors that you have noted be successfully addressed? What constitutes success and what are the binding constraints?

Please use evidence, where possible, from sub-Saharan African countries.

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1. Overview

Medicines are integral of any healthcare system, and limited access to medicines undermines health systems' objectives of equity, efficiency and health development. In African countries, where it is estimated that 50–60% of the populace lack “access” to essential medicines, health problems associated with limited drug benefits are more damaging.

The main **barriers** to essential medicines in Sub Saharan Africa were found to be as follows:

- Inadequate national commitment to making healthcare a priority from the national to the local levels remains one of the greatest barriers to increasing access to existing medicines.
- Inadequate human resources for health, including pharmacists and pharmacy technicians, is a growing problem that, if unaddressed, threatens to undermine all efforts to strengthen health systems and improve healthcare in much of the developing world.
- The international community has not provided adequate finance nor consistently fulfilled its existing promises to developing countries.
- A persistent lack of coordination of international aid reduces access to medicines.
- The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement may block access to affordable new medicines and vaccines.
- The current incentive structure is inadequate to promote research and development of medicines and vaccines to address priority health problems of developing countries.

The following is an overview of some of the **solutions** presented in the evidence:

National procurement

- Generic competition will also bring gains, though these may differ between different income groups. Enterprises could be persuaded to provide free, or subsidized, medicines for their employees, by the expenditures being allowed against liabilities for profits tax.
- Competition from generic substitutes (whenever available) may have three beneficial effects:
 1. They will help bring about a decrease in the price of the patented medicine.
 2. Being lower-priced products, they could be more accessible to some lower-income groups (though perhaps not to those with the very lowest incomes).
 3. They could reduce the amount of funds required for a government subsidy.
- Context-specific policies are required to improve access to essential medicines. Generic products should be promoted by educating professionals and consumers, by implementing appropriate policies and incentives, and by introducing market competition and/or price regulation. Improving governance and management efficiency, and assessing local supply options, may improve availability. Prices could be reduced by improving purchasing efficiency, eliminating taxes and regulating mark-ups.
- Hard bargaining, country-specific, price-sensitive purchasing agencies provide a sustainable mechanism for making essential medicines affordable to African households.
- Development partners and the international community must provide the necessary support for institution of country-specific purchasing agencies. Investing in these procurement agencies will be in line with efforts for strengthening healthcare systems capacity in African nations.

- Market regulation by governments does not necessarily negatively affect drug availability; in fact, given the reduction in prices, access to more affordable essential medicines may improve with regulation.
- More assertive policies, based on strategies encompassing actors in the private sector, are needed to increase the safety and effectiveness of prescription and sales practices.
- An important first step in reducing prices will be to make available in the public domain as much drug transaction data as possible to provide a factual basis for discussions on pricing.
- Drawing lessons from various experiences, one could argue that successful financing of medicines is contingent upon a number of factors, as outlined below:
 1. Political commitment
 2. Effective design and administrative capacity
 3. Clear implementation strategies
 4. Financial sustainability
 5. Rational selection and rational drug use
 6. Affordable prices
 7. Reliable medicine supply systems and low taxes
- There is not a "one size- fits-all" policy menu that should be applied across Africa. Governments need to make informed policy choices when it comes to improving access to medicines and assess which measures are most needed and viable for their particular country.

Quality of medicines

- To address the fact that many developing countries lack suitable regulators it has been argued that:
 1. It is better for developing countries to rely on the assessments of major medicines regulatory authorities, such as those in the US and Europe, when faced with an application for registration of an NCE.
 2. Regional co-operation is needed when considering applications for IMMs, as the needed expertise is also in short supply.
 3. In specific areas, the WHO pre-qualification programme may assist developing countries.
- Donors should encourage their partners to include more explicit quality requirements in their tender mechanisms, while purchasers should insist that producers and distributors supply drugs that comply with international quality standards. Governments in rich countries should not tolerate the export of substandard pharmaceutical products to poor countries, while developing country governments should improve their ability to detect substandard medicines.

National supply, storage and distribution systems

- Sound coordination is needed between public medicine wholesalers and their clients to harmonize procurement and consumption as well as with vertical programmes to prevent duplicate procurement.
- National medicine regulatory authorities should enforce existing international guidelines to prevent dumping of donated medicine.

Human resources barriers

- To address scaling up of essential medicines, the following human resources action would include at a minimum:
 1. Promoting international action on the brain drain;
 2. At country level (re)investment in traditional human resource functions such as planning, production, remuneration and management of health care providers;
 3. Addressing macro-economic constraints on employment and remuneration of health care providers;
 4. Evaluation of the performance of existing nationally developed cadres such as mid-level and community health workers and their potential role in HIV treatment scale-up.
- Training of community health workers to deliver some essential services and stimulation of demand through improved outreach and education will be needed for essential medicine to be widely available.

Facility level barriers

- At the facility level, it is clear that a strengthened supply chain system, proper stock management by qualified staff and sufficient budget for drug procurement will improve availability of essential medicines.
- In order to ensure equitable access to life saving drugs, logistics in general should be put in order before specific disease management programmes are initiated.

Patents barriers

- Compulsory licensing is a potentially powerful tool that developing nations can use to circumvent patent laws and give their residents access to life-saving medicines
- Under some circumstances states are not merely permitted compulsory to license inventions, but are actually obliged to do so, on pain of failure of their legitimacy as sovereign states.
- Developed countries and pharmaceutical companies may have the duty under international law to ensure that their actions do not by any means hinder access to medicines for those in poor countries of the world.

There is considerable overlap between the sections, with many of the papers reviewed focusing on two or more topics. Each paper has been placed in the section most relevant to its main theme, but many are relevant to other sections as well.

Where possible for each key paper in section 2, the key strategies to successfully address the constraints to access to essential medicines have been highlighted.

The report focuses on evidence from sub-Saharan African countries.

2. a. National procurement systems

Katrak, H. 2004, Affordable Prices for Essential Medicines for Developing Countries: Some Economic Issues. *Development Policy Review* 22 (3), 309-320, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=531304

This article discusses recent developments that may help bring about more affordable prices of essential medicines for developing countries. It argues that the governments of these countries should support campaigns for affordable prices. Generic competition will also bring gains, though these may differ between different income groups. Enterprises could be persuaded to provide free, or subsidised, medicines for their employees, by the expenditures being allowed against liabilities for profits tax. The UN Global Fund could complement the efforts of public action groups, enhance a government's fiscal capabilities and also encourage other measures to reduce the costs of providing medicines.

The focus of the paper is the role of public action campaigns to bring about lower prices of patented medicines, the growth of generic competition and some recent enterprise level initiatives. Affordable price in this case is defined as the price that would either enable all infected persons to purchase their medicines or enable the government to provide subsidised medicines for those too poor to make their own purchases. It was shown that the affordable price has to be lower, the greater the proportion of the country's population that has been infected; the lower the average income of these persons, the less even is the distribution of those incomes and the lower the amount of funds that the government can collect for a subsidy.

Competition from generic substitutes (whenever available) may have three beneficial effects:

- 1) They will help bring about a decrease in the price of the patented medicine.
- 2) Being lower-priced products, they could be more accessible to some lower-income groups (though perhaps not to those with the very lowest incomes).
- 3) They could reduce the amount of funds required for a government subsidy.

Mendis, S. Et al. 2007, The availability and affordability of selected essential medicines for chronic diseases in six low- and middle-income countries. *Bulletin of the World Health Organization*; 85 (4)

<http://www.who.int/bulletin/volumes/85/4/06-033647.pdf>

This paper assesses the availability and affordability of medicines used to treat cardiovascular disease, diabetes, chronic respiratory disease and glaucoma and to provide palliative cancer care in six low- and middle-income countries. A survey of the availability and price of 32 medicines was conducted in a representative sample of public and private medicine outlets in four geographically defined areas in Bangladesh, Brazil, Malawi, Nepal, Pakistan and Sri Lanka. Analysis of the percentage of these medicines available was completed, including the median price versus the international reference price (expressed as the median price ratio) and affordability in terms of the number of days' wages it would cost the lowest-paid government worker to purchase one month of treatment.

It was found that in all countries < 7.5% of these 32 medicines were available in the public sector, except in Brazil, where 30% were available, and Sri Lanka, where 28% were available. Median price ratios varied substantially, from 0.09 for losartan in Sri Lanka to 30.44 for aspirin in Brazil. In the private sector in Malawi and Sri Lanka, the cost of innovator products (the pharmaceutical product first given marketing authorisation) was three times more than generic medicines. One month of combination treatment for coronary heart disease cost 18.4 days' wages in Malawi, 6.1 days' wages in Nepal, 5.4 in Pakistan and 5.1 in Brazil; in Bangladesh the cost was 1.6 days' wages and in Sri Lanka it was 1.5. The cost of one month of combination treatment for asthma ranged from 1.3 days' wages in Bangladesh to 9.2 days' wages in Malawi. The cost of a one-month course of intermediate-acting insulin ranged from 2.8 days' wages in Brazil to 19.6 in Malawi.

Context-specific policies are required to improve access to essential medicines. Generic products should be promoted by educating professionals and consumers, by implementing appropriate policies and incentives, and by introducing market competition and/or price

regulation. Improving governance and management efficiency, and assessing local supply options, may improve availability. Prices could be reduced by improving purchasing efficiency, eliminating taxes and regulating mark-ups.

Tettah, E. 2008, Providing affordable essential medicines to African households: The missing policies and institutions for price containment. *Social Science & Medicine* 66 569–581

<http://www.sciencedirect.com/science/article/pii/S0277953607005400>

Medicines are integral of any healthcare system, and limited access to medicines undermines health systems' objectives of equity, efficiency and health development. In African countries, where it is estimated that 50–60% of the populace lack "access" to essential medicines, health problems associated with limited drug benefits are more damaging. However, there is no single solution to medicine access problem given its multiple dimensions: availability, acceptability, affordability and accessibility.

This paper explores affordability dimension of medicine access and concentrates solely on price regulatory policies and institutional structures that national and international policy makers may consider in making prices of essential drugs compatible to the purchasing power of African households. The main theme is the application of the concept of bilateral dependence in creating price-sensitive purchasers to exert countervailing market power on drug price setting in African healthcare systems.

Hard bargaining, country-specific, price-sensitive purchasing agencies represent a more sustainable mechanism for making essential medicines affordable to African households. The bilateral dependence solution is an institutional response that allows African nations to take charge of their own public affairs. Development partners and the international community, whose aim is to help African nations help themselves, must provide the necessary support for institution of country-specific purchasing agencies. Investing in these procurement agencies will be in line with efforts for strengthening healthcare systems capacity in African nations.

Ruxin, J. Et al. 2005, Emerging consensus in HIV/AIDS, malaria, tuberculosis, and access to essential medicines. *Lancet*; 365: 618–21

<http://www.unmillenniumproject.org/documents/TheLancetHealth.pdf>

Lasting control of AIDS, tuberculosis, and malaria will depend on strengthening health systems as well as disease-specific programmes. Doing so will require sustained investment in physical infrastructure, drug distribution systems, management at all levels, and, most importantly, human resources. In many countries, salaries will have to be increased substantially to recruit and retain a motivated health-care workforce and to stem the loss of skilled staff to the developed world. As health systems are expanded and improved, existing practical approaches can be deployed rapidly and could save millions of lives. These approaches may include, for example, training of community health workers to deliver some essential services and stimulation of demand through improved outreach and education.

Upgrading of health systems in the poorest countries will require focused, long-term funding from international donors, and consistent political commitment from donors and recipients alike. Although funding for global public health (especially the fight against AIDS) has expanded in recent years, it remains insufficient, largely short-term, poorly coordinated, and unpredictable, as evidenced by the funding shortfalls faced by the Global Fund to Fight AIDS, Tuberculosis and Malaria. The failure of developed countries to fulfil their longstanding pledges of more development aid, and the failure of developing countries themselves to invest in health, are overarching barriers to health systems development.

Furthermore, the lack of coordination among international financial institutions, bilateral donors, and non-governmental organisations exhausts scarce resources and duplicates

effort. Success will require more than increased public funding. Private partners must also be engaged in new ways to expand demand and access to high-quality services and to help compensate for the shortage of human resources in the public sector. Removing bottlenecks calls for improved priority-setting and strategic innovation at the local, national, and global level. Moreover, health services must be financed equitably. User fees, for example, are an important barrier to health-care access for the poor and should be abolished.

These strategies must be led by countries themselves: they cannot be imposed from the outside. However, donor nations, international institutions, and activists have a responsibility to ensure that funding is not the critical barrier to countries' efforts to reach the MDGs. The countries, in turn, must spearhead the effort by increasing their own investment in health systems and establishing strict monitoring and evaluation to show results.

Chaudhuri, S. Et al. 2010, Indian Generics Producers, Access to Essential Medicines and Local Production in Africa: An Argument with Reference to Tanzania. *European Journal of Development Research* 22, 451–468.

<http://www.palgrave-journals.com/ejdr/journal/v22/n4/full/ejdr201027a.html>

Much analysis of the supply chain for essential medicines to Africa assumes broad sustainability of low-cost generics supply from Indian manufacturers. This paper uses Indian data and interviews to question this assumption. Using a case study of Tanzania, the necessity and feasibility of enhanced local production of essential medicines are discussed. Key industrial policy interventions are identified, including industrial protection and active government purchasing; public goods including legislative and regulatory frameworks and training; and encouragement and facilitation of joint ventures.

It was found that Tanzania will face severe problems in improving access to essential medicines for its population if it continues to rely heavily on foreign exporting sources such as India. Local production already contributes importantly to access to essential medicines by the poorest part of the population. Its further development can reduce dependence on foreign exporters, make supplies more reliable, enhance local price competition, and make it easier for drug control administration to ensure quality. There are thus major developmental and health benefits to be gained from an effective industrial policy to promote development of the local pharmaceutical industry.

There exists a feasible set of policy interventions available to promote market development, investment and technological upgrading. Indian experience provides some guide, although Tanzania faces immense disadvantages of context and timing. Furthermore, there are indicators in experience to date of Tanzanian government competence to pursue an industrial policy agenda in this sector. A major programme of industrial upgrading is required, led by government integration of health policy needs with industrial policy activism.

Maigaa, D. & Williams-Jones, B. 2010, Assessment of the impact of market regulation in Mali on the price of essential medicines provided through the private sector. *Health Policy* 97, 130–135

http://umontreal.academia.edu/BrynWilliamsJones/Papers/390388/Assessment_of_Regulation_as_a_Solution_to_the_High_Prices_of_Essential_Medicines_in_the_Private_Sector_of_Mali

In 1998, the government of Mali adopted a national pharmaceutical policy aimed at promoting a supply system for generic essential medicines that would guarantee equal access for all citizens. Distribution and delivery is a shared responsibility of both public and private sectors (wholesalers and pharmacies). To influence private sector behaviour, the national policy uses a combination of government regulation and market forces. In 2006, the government issued a decree fixing maximum prices in the private sector for 107 prescription drugs from the national list of 426 essential medicines. The current study assessed the impact of this

intervention on the evolution of market prices (wholesale and retail), and the subsequent availability and public access to essential medicines in Mali. This was achieved by conducting a cross-sectional descriptive survey in February and May 2006, and January 2009, with 16 wholesalers and 30 private drugstores in Bamako, Mali.

The results found that the overall availability of essential medicines at private wholesalers ($p = 1$) and pharmacies ($p = 0.53$) was identical before and after the enforcement of the 2006 decree fixing maximum drug prices. Contrary to concerns expressed by wholesalers and pharmacies, and the other stakeholders, the decree did not impact negatively on availability of essential medicines. In fact, median wholesale prices in 2009 were 25.6% less than those fixed by the decree. In private pharmacies, retail prices were only 3% more expensive than the recommended prices, compared with being 25.5% more expensive prior to enforcement of the decree.

The study shows that prices of essential medicines in Mali have evolved favourably towards the prices recommended by the government decree. Further, the study contributes to mounting evidence that market regulation by governments does not necessarily negatively affect drug availability; in fact, given the reduction in prices, the study shows that Malians arguably have better access to more affordable essential medicines.

Cameron, A. Et al. 2009, Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. *Lancet*, 373: 240–49
<http://www.sciencedirect.com/science/article/pii/S0140673608617626>

WHO and Health Action International (HAI) have developed a standardised method for surveying medicine prices, availability, affordability, and price components in low-income and middle-income countries. This paper presents a secondary analysis of medicine availability in 45 national and sub-national surveys done using the WHO/HAI methodology.

Data from 45 WHO/HAI surveys in 36 countries were adjusted for inflation or deflation and purchasing power parity. International reference prices from open international procurements for generic products were used as comparators. Results are presented for 15 medicines included in at least 80% of surveys and four individual medicines.

It was found that average public sector availability of generic medicines ranged from 29.4% to 54.4% across WHO regions. Median government procurement prices for 15 generic medicines were 1.11 times corresponding international reference prices, although purchasing efficiency ranged from 0.09 to 5.37 times international reference prices. Low procurement prices did not always translate into low patient prices. Private sector patients paid 9–25 times international reference prices for lowest-priced generic products and over 20 times international reference prices for originator products across WHO regions. Treatments for acute and chronic illness were largely unaffordable in many countries. In the private sector, wholesale mark-ups ranged from 2% to 380%, whereas retail mark-ups ranged from 10% to 552%. In countries where value added tax was applied to medicines, the amount charged varied from 4% to 15%.

Overall, public and private sector prices for originator and generic medicines were substantially higher than would be expected if purchasing and distribution were efficient and mark-ups were reasonable. Policy options such as promoting generic medicines and alternative financing mechanisms are needed to increase availability, reduce prices, and improve affordability.

Cohen, J. Et al. 2005. TRIPS, the Doha Declaration and increasing access to medicines: policy options for Ghana. *Globalization and Health*, 1:17
<http://www.globalizationandhealth.com/content/1/1/17>

There are acute disparities in pharmaceutical access between developing and industrialised countries. Developing countries make up approximately 80% of the world's population but only represent approximately 20% of global pharmaceutical consumption. Among the many barriers to drug access are the potential consequences of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Many developing countries have recently modified their patent laws to conform to the TRIPS standards, given the 2005 deadline for developing countries. Safeguards to protect public health have been incorporated into the TRIPS Agreement; however, in practice governments may be reluctant to exercise such rights given concern about the international trade and political ramifications. The Doha Declaration and the recent Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health may provide more freedom for developing countries in using these safeguards. This paper focuses on Ghana, a developing country that recently changed its patent laws to conform to TRIPS standards. Ghana's patent law changes are examined in the context of the Doha Declaration and assess their meaning for access to drugs of its population. New and existing barriers are discussed, as well as possible solutions, to provide policy-makers with lessons learned from the Ghanaian experience.

Several possibilities for working within the TRIPS regime to gain better access of the population to medicines are presented. These options include compulsory licensing, parallel importing, technology transfer, local production and voluntary differential pricing.

Ghana and its Access to Medicines (ATM) Advisory Committee are encouraged to consider local production. Local manufacturing can be an effective option if human and technological capacity is scaled up. However, this option should only be pursued if it makes economic sense. As a start, an objective cost-benefit analysis should be done to determine whether it makes economic sense for Ghana to pursue local production.

Among the alternatives available to strengthen local industry include more aggressive technology transfer. The use of compulsory licensing should be encouraged. If Ghana decides to pursue compulsory licensing, it must then address administrative and knowledge barriers. This can be achieved through obtaining support from developed countries and/or international organisations on the effective implementation of compulsory licensing. There is great potential for Ghana particularly given the Government's commitment to build up its knowledge base in this area. Ghana will have to establish insufficient manufacturing capacity in the pharmaceutical sector in question, and then consider what political or economic repercussions may follow. More concrete alternatives for importation include parallel importation or the voluntary tiered-pricing arrangement proposed by the European Commission. Importantly, it is critical to monitor any public policy reform to assess whether or not they are achieving attendant outcomes and adjust accordingly. This will require baseline assessments and regular review at intervals.

The development and implementation of an effective exemption policy for the poor without co-payments is vital. Policies can vary such as implementing a national pricing policy that control prices on the supply side by regulating actual drug costs or the demand side, through reimbursement schemes such as reference-based pricing or generic substitution policies. Furthermore, reduction of mark-ups in the public sector may generate competition and drive private sector prices down. A hard but necessary policy reform is needed in the area of national tax, tariff and mark-ups to determine what changes could facilitate more affordable prices for the population.

There is not a "one size- fits-all" policy menu that should be applied across Africa. Governments need to make informed policy choices when it comes to improving access to medicines and assess which measures are most needed and viable for their particular country.

Klug, H. 2008, Law, Politics, and Access to Essential Medicines in Developing Countries. *Politics Society*; 36 (207)
<http://pas.sagepub.com/content/36/2/207>

This article argues that to advance the struggle for access to essential medicines, it is necessary to identify the global and local regimes that shape the rules that give impetus to particular policy options, while undermining others. In exploring the role of law and politics in this process, the author first outlines the globalisation of a standardised, corporate-inspired, intellectual property regime. Second, the author uses the example of the HIV/AIDS pandemic to demonstrate how the stability of this new regime came under pressure, both locally and globally.

Finally, it is argued that while the global HIV/AIDS pandemic and the social movements that emerged in response to government inaction have effectively challenged the TRIPS regime, this complex contestation has reached an unsustainable stalemate in which development aid, corporate, and non-governmental philanthropy is simultaneously providing increased availability to drugs while precluding a more lasting solution to the crisis of access to essential medicines in developing countries.

Maiga, F. Et al. 2003, Public and private sector responses to essential drugs policies: a multilevel analysis of drug prescription and selling practices in Mali. *Social Science & Medicine* 57; 937–948
http://econpapers.repec.org/article/eesocmed/v_3a57_3ay_3a2003_3ai_3a5_3ap_3a937-948.htm

Many African countries have introduced cost recovery mechanisms based on the sale of drugs and measures aimed at improving drug supply. This study compares prescribing and selling practices in Mali, in 3 cities where the public sector contributes differentially to the supply of drugs on the market. Multilevel models are used to analyse the content and cost of 700 medication transactions observed in 14 private and public legal points of sale. Results show that the objective of improving access to drugs seems to have been achieved in the sites studied. Costs of prescriptions were lower where public health services had been revitalised. Affordable generic drugs were accessible and widely used, even in the private sector. However, measures intended to rationalise the prescription and delivery of drugs did not always have the desired effect. While agents in the public sector tended to prescribe fewer antibiotics, injectables, or brand-name drugs, the data confirm the virtual absence of advice concerning the use or the side effects of the drugs in both public and private sectors. In addition, data supported the notion that the public and private sectors are closely intertwined. Notably, availability of drugs in the public sector contributed to diminishing the prices charged in the private sector. Similarly, the use that agents in the public sector made of the opportunities afforded by the presence of the private pharmaceutical sector provided another illustration of interrelatedness. Finally, the data showed that the presence of a private sector, which has not been affected by measures aimed at rationalising prescription and sales practices, limits the effects of measures implemented in the public sector. More assertive policies, based on strategies encompassing actors in the private sector, are needed to increase the safety and effectiveness of prescription and sales practices.

Leach, B. Et al. 2005, *Prescription for healthy development, increasing access to medicine*. UN Millennium Project
<http://www.unmillenniumproject.org/documents/TF5-medicines-Complete.pdf>

In this paper, the Working Group on Access to Essential Medicines of the Task Force on AIDS, Malaria, TB, and Access to Essential Medicines underscores the vital need to increase the availability, affordability, and appropriate use of medicines in developing countries. The working group proposes concrete and practical steps to increase incentives for research for priority diseases of developing countries, improve procurement and distribution, strengthen

primary health systems, develop more human resources, and increase health funding. These are all necessary components of a comprehensive strategy to improve access to essential medicine in developing countries.

Barriers that were identified to existing medicines include:

- Inadequate national commitment to making healthcare a priority from the national to the local levels remains one of the greatest barriers to increasing access to existing medicines. There are many reasons for this lack of prioritisation. Key among them are a lack of political will by policymakers to make the needs of the poor a priority; donor programs that can skew or limit national governments' abilities to set health policy; debt servicing and conditionality for loans from international financial institutions that can further limit government responsiveness to basic social service needs of citizens; and, unfortunately, the threat of corruption that continues in the healthcare sector at all levels.

- Inadequate human resources for health, including pharmacists and pharmacy technicians, is a growing problem that, if unaddressed, threatens to undermine all efforts to strengthen health systems and improve healthcare in much of the developing world. Education, information, and in-service training remain potent tools to change that situation. More needs to be done to identify what is needed to retain skilled workers, especially in the face of mounting demands for health workers, such as nurses and pharmacists, in developed countries. Retention plans and compensation schemes for countries that lose health workers should be investigated.

- The international community has not provided adequate finance nor consistently fulfilled its existing promises to developing countries. Some proposed actions have not been carried out at all and others have not been carried out effectively. To achieve progress, there will be a need for political will, in both industrialised and developing countries, as well as a need for transparency on all fronts. Above all, there will be a need for increased levels of long-term financial support from the world community. It remains an unfortunate ongoing reality that some of the world's wealthiest countries remain the farthest from achieving their longstanding commitment to the international development assistance target of 0.7 percent of gross domestic product (GDP).

- A persistent lack of coordination of international aid reduces access to medicines. Most poor countries will require significant donor funding to achieve universal access to essential medicines. They will also need much better aid coordination to avoid unnecessarily heavy reporting requirements and to avoid resource-wasting duplication of efforts. Sector-wide approaches should be used to promote improved coordination. Donors should commit aid that strengthens existing systems, that proactively targets the poorest and rural areas, and that avoids vertical programming by disease or by a given donor. A need exists at both the international and national levels for a great deal more transparency and coordination of effort between the large number of organisations that have already become involved in one way or another in this field. The involvement of so many bodies can and does lead to duplication of effort and to waste, and both are unacceptable. In some situations, there is every reason to merge complementary ventures. Pharmaceutical companies can and should contribute in their own particular way to the advancement of national medicines policies and the development of capacity in this field.

Barriers to the development of affordable new medicines include:

- The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement may block access to affordable new medicines and vaccines. After January 2005, generic production in India, the source of many vital existing medicines for developing countries without productive capabilities, will be fully subject to TRIPS provisions.

- The current incentive structure is inadequate to promote research and development of medicines and vaccines to address priority health problems of developing countries. For a

number of the most neglected diseases (such as African trypanosomiasis, Chagas disease, leishmaniasis, and dengue fever), which occur primarily in developing countries, new medicines need to be developed. For others, new medicines are needed to address shortcomings of existing treatments, such as safety, efficacy, appropriate dosing, length of treatment, and the ongoing threat of drug resistance. Despite progress in funding research and development (R&D) for new medicines for neglected diseases, with notable contributions from philanthropic foundations and some governments and pharmaceutical companies, more financial resources need to be mobilised in a sustainable way to create a strong and sustainable pipeline of new products. New thinking, different means of financing and organising medicines development, and other reforms are needed. For example, the WHO Commission on Intellectual Property Rights, Innovation, and Public Health should examine alternative international models to the current patent-based system for priority setting and financing of health R&D.

Twagirumukiza, M. Et al. 2010, Prices of antihypertensive medicines in sub-Saharan Africa and alignment to WHO's model list of essential medicines. *Tropical Medicine and International Health* 15 (3)

<http://www.ncbi.nlm.nih.gov/pubmed/20070634>

This paper aims to investigate compliance of National Essential Medicines Lists (NEMs) with the WHO Essential Medicines List (WHO/EML) in 2007 and to compare prices of antihypertensive drugs in and between 13 sub-Saharan African countries. Data on NEMs and drug prices were collected from 65 public and 65 private pharmacies (five of each per country). Prices were compared with the International Drug Price Indicator Guide (IDPIG). The cost of drug treatment within a country was calculated using defined daily doses (DDD) and between countries using DDD prices adjusted for purchasing power parity-based gross domestic product per capita.

The results indicate that all surveyed countries had a NEM. However, none of these lists were in complete alignment with the 2007 WHO/EML, and 38% had not been updated in the last 5 years. Surveyed medicines were cheaper when on the NEMs; they were also cheaper in public than in private pharmacies. Prices varied greatly per medicine. A large majority of the public prices were higher than those indicated by the IDPIG. Overall, hydrochlorothiazide is the cheapest drug.

The study concludes that there are substantial differences in NEM composition between the 13 countries. The proportion of NEMs not regularly updated was double the global United Nations estimates. Prices of WHO/EML-advised drugs differ greatly between drugs and for each drug within and between countries. In general, the use of drugs on the NEM improves financial accessibility, and these drugs should be prescribed preferentially.

Vasan, A. Et al. 2006, The pricing and procurement of antiretroviral drugs: an observational study of data from the Global Fund. *Bulletin of the World Health Organization*; 84: 393-398.

<http://www.who.int/bulletin/volumes/84/5/393.pdf>

The Purchase price report released in August 2004 by the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund) was the first publication of a significant amount of real transaction purchase data for antiretrovirals (ARVs). The authors completed an observational study of the ARV transaction data in the Purchase price report to examine the procurement behaviour of principal recipients of Global Fund grants in developing countries. They found that, with a few exceptions for specific products (e.g. lamivudine) and regions (e.g. eastern Europe), prices in low-income countries were broadly consistent or lower than the lowest differential prices quoted by the research and development sector of the pharmaceutical industry. In lower middle-income countries, prices were more varied and in several instances (lopinavir/ritonavir, didanosine, and zidovudine/lamivudine) were very high

compared with the per capita income of the country. In all low- and lower middle-income countries, ARV prices were still significantly high given limited local purchasing power and economic strength, thus reaffirming the need for donor support to achieve rapid scale-up of antiretroviral therapy. However, the price of ARVs will have to decrease to render scale-up financially sustainable for donors and eventually for governments themselves. An important first step in reducing prices will be to make available in the public domain as much ARV transaction data as possible to provide a factual basis for discussions on pricing. The price of ARVs has considerable implications for the sustainability of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) treatment in the developing world.

Mercurio, B. 2007, *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines*. University of New South Wales - Working paper 23.

<http://law.bepress.com/unswwps-flrps/art23>

This article examines the many factors that have created and continue to perpetuate the ongoing health crisis in developing countries. In so doing, the article reveals that the focus on patent regulation is largely misguided and that the targeting of pharmaceutical companies and TRIPS has led to an unfortunate divergence from the actual critical issues that affect the delivery of much-needed care and medicines to the developing world. It then argues that the critical issues lie not in constructing appropriate TRIPS provisions, but more so in providing financial resources to build, maintain and stabilise proper healthcare systems in those developing countries afflicted with public health crises.

This article does not fully absolve pharmaceutical companies from blame nor does it claim that TRIPS strikes the appropriate balance between creators and users in every situation, but much has already been written on these two issues. Instead, it focuses on and examines possible solutions or initiatives that may be adopted to alleviate the current public health problems and assesses their practicability in light of the particular situations and circumstances affecting the developing world.

Nunan, M & Duke, T. 2011, Effectiveness of pharmacy interventions in improving availability of essential medicines at the primary healthcare level. *Tropical Medicine and International Health*; 16 (5)

<http://www.ncbi.nlm.nih.gov/pubmed/21342375>

This paper aims to assess the effectiveness of pharmaceutical systems interventions in improving the availability of essential medicines at the primary care level. Examples of pharmaceutical systems were searched for in the literature, as were interventions in low and middle income countries that evaluated the impact of specific interventions on medicines' availability. Qualitative and quantitative studies were included. Seventeen studies were included, on privatisation of drug distribution, user-fees, revolving drug funds (RDFs), supervisory visitation programmes, staff training initiatives, community-directed interventions (CDIs) and disease-specific drug programmes. We found no studies on non-monetary staff incentives or the use of national pharmacy standards. Generally, the quantity and quality of evidence was low; evidence was strongest for supervisory visitation programmes and CDIs.

It was found that several interventions have the potential for improving medicines' availability without requiring large-scale international cooperation or global policy change. The absence of evidence in this field does not prove lack of effect. There is a need for more systematic studies of multi-faceted pharmaceutical interventions to improve drug availability in the context of difficult health systems, such as structured supervision of remote health facilities, CDIs, staff training, integration of disease-specific programmes, implementation of national pharmacy standards, non-monetary staff incentives and measures to ensure cost is not a barrier to access. A standardised approach to measuring the availability of essential medicines is needed.

Kanavos, P. Et al. 2010, *Options for financing and optimizing medicines in resource-poor countries*. World Health Report (2010) Background Paper, 34
<http://www.who.int/healthsystems/topics/financing/healthreport/34Medicinesrev.pdf>

This paper discusses various options for resource-poor countries to enhance access to, and minimise household out-of-pocket spending, on medicines. Specific options discussed in this paper are

- Taxation
- Social health insurance
- Private health insurance
- Community financing
- Drug sales and revolving funds
- Medical savings accounts

Drawing lessons from various experiences, one could argue that successful financing of medicines is contingent upon a number of factors, as outlined below:

- Political commitment
- Effective design and administrative capacity
- Clear implementation strategies
- Financial sustainability
- Rational selection and rational drug use
- Affordable prices
- Reliable medicine supply systems and low taxes

See table 10 (page 54) for more details on options for financing medicines in developing countries.

2. b. Quality assessment of products

Gray, A. 2004, *Access to Medicines and Drug Regulation in Developing Countries: a Resource Guide for DFID*. DFID Health Systems Resource Centre, London
<http://www.bvsde.paho.org/bvsacd/cd65/Gray.pdf>

Medicines registration is the process by which a national or regional MRA approves the use of a medicine in a particular country, having considered evidence of the medicine's safety, quality and efficacy. It is thus primarily concerned with protecting public health. However, where medicines regulatory processes are unwieldy and delay entry of needed medicines in a particular market, they can be seen as a barrier to access as well as to profits and the growth of the pharmaceutical industry. Premarketing assessment of safety, quality and efficacy is however only one component of a medicines regulatory system. In addition, attention must be paid to ongoing assessment and inspection of the entire pharmaceutical supply chain (including manufacturers, importers, exporters, wholesalers, distributors and final sellers), maintenance of a register of approved products and post-marketing surveillance (including random quality checks and pharmacovigilance systems), control over the promotion and advertising of medicines and the provision of medicines information. Lastly, there is a view that issues related to the rational pricing of medicines and considerations of cost-effectiveness may also legitimately fall within the ambit of the medicines regulatory agency.

Developing country regulators are often under-resourced and lack access to the high levels of scientific expertise needed for the effective assessment of registration dossiers for new chemical entities (NCEs) and interchangeable multi-source medicines (IMMS, or 'generics'). To address these issues, it has been argued that:

- It is better for developing countries to rely on the assessments of major medicines regulatory authorities, such as those in the US and Europe, when faced with an application for registration of an NCE.
- Regional co-operation is needed when considering applications for IMMs, as the needed expertise is also in short supply.
- In specific areas, the WHO pre-qualification programme may assist developing countries.

Patel, A. Et al. 2009, Drug quality in South Africa: perceptions of key players involved in medicines distribution *International Journal of Health Care Quality Assurance* 22 (5)
<http://leeds2.emeraldinsight.com/journals.htm?issn=0952-6862&volume=22&issue=5&articleid=1805788&show=pdf&PHPSESSID=7kclpj91a9j6dq2m4d727m7836>

The purpose of this paper is to explore pharmaceutical manufacturers', distributors' and providers' perceptions of drug quality in South Africa and how they ensure the quality of drugs during the distribution process. Substandard medicines contribute to poor public health and affect development, especially in the developing world. However knowledge of how manufacturers, distributors and providers understand the concept of drug quality and what strategies they adopt to ensure drug quality is limited, particularly in the developing world.

For this study qualitative data was collected through key informant interviews using a semi-structured interview guide. Participants were recruited purposefully from a South African pharmaceutical manufacturer, SA subsidiaries of international manufacturers, national distribution companies, national wholesaler, public and private sector pharmacists, and a dispensing doctor. In total, ten interviews were conducted.

Participants described drug quality in terms of the product and the processes involved in manufacturing and handling the product. They also identified purchasing registered medicines from licensed suppliers, use of standard operating procedures, and audits between manufacturer and distributor and/or provider as key strategies employed to protect medicine quality. Effective communication amongst all stakeholders, especially in terms of providing feedback regarding complaints about medicine quality, appears as a potential area of concern, which would benefit from further research.

The paper highlights that ensuring medicine quality should be a shared responsibility amongst all involved in the distribution process to prevent medicines moving from one distribution system (public) into another (private).

Caudron, J. et al. 2008, Substandard medicines in resource-poor settings: a problem that can no longer be ignored. *Tropical Medicine and International Health*; 13 (8)
http://msf.openrepository.com/msf/bitstream/10144/37334/1/Caudron_substdmeds_TMIH2008.pdf

The circulation of substandard medicines in the developing world is a serious clinical and public health concern. Problems include under or over concentration of ingredients, contamination, poor quality ingredients, poor stability and inadequate packaging. There are multiple causes. Drugs manufactured for export are not regulated to the same standard as those for domestic use, while regulatory agencies in the less-developed world are poorly equipped to assess and address the problem. A number of recent initiatives have been established to address the problem, most notably the WHO pre-qualification programme. However, much more action is required. Donors should encourage their partners to include more explicit quality requirements in their tender mechanisms, while purchasers should insist that producers and distributors supply drugs that comply with international quality standards. Governments in rich countries should not tolerate the export of substandard pharmaceutical

products to poor countries, while developing country governments should improve their ability to detect substandard medicines.

Mhamba, R. M. & Mbirigenda, S. 2010, *The drugs industry and access to essential medicines in Tanzania*. EQUINET Discussion Paper Series 83 Training and Research Support Centre, SEATINI, Rhodes University, EQUINET: Harare
<http://www.equinet africa.org/bibl/docs/DIS83TZN%20medicines%20mhamba.pdf>

This paper outlines the flows of private capital that lie behind the growth of the for-profit pharmaceutical sector in Tanzania, and analyses the policy, access and equity challenges posed by the shift to increasing private sector participation in medicine provision.

The Tanzanian drug policy specifically highlights the government's intention to ensure that quality, effective essential medicines reach all Tanzanians at an affordable price. Using case study examples, this study explored the concept of access to essential medicines in four dimensions: physical availability, affordability, geographic accessibility, and acceptability (or satisfaction) defined as the fit between users' and providers' attitudes and expectations about products and services and the actual characteristics of these products and services.

Three pharmaceutical companies involved in Public-Private Partnerships (PPPs) were studied — two in Dar es Salaam city (Shelys and Keko) and one in Arusha town (Tanzanian Pharmaceutical Industry (TPI)). Data was also collected from the relevant government ministries, departments, and agencies; and development partners: Data collection included documentary reviews of various studies and reports from pharmaceutical companies, the government, donors and other stakeholders, followed by a review of the existing government policies, legislation and guidelines for the pharmaceutical sector. Documentary analysis aimed to:

- Identify and analyse existing policies, legal framework, and guidelines dealing with capital flows in the pharmaceutical sector, local pharmaceutical production, marketing, and the links to local procurement; and
- Examine distribution systems and the demand for the locally produced drugs to identify strengths and critical gaps.

The study found that the quality of medicines manufactured in Tanzania was often inadequate, with Tanzania's general manufacturing practices (GMP) being lower than international standards, and with government failing to adequately monitor even those standards. Only two of the eight pharmaceutical manufacturers are meeting the standards — in the case of TPI this is thanks to funding from development partners and in the case of Shelys, it is thanks to foreign direct investment from Aspen Holdings. While TPI can be considered to be improving access to medicine at an affordable price in Tanzania, a substantial portion of Shelys' production (41%) is not for local consumption and is exported to other countries. Shelys is also not concerned with producing medicine at affordable prices for Tanzanians, but more interested in profit generation.

TPI's production — focussed on antiretroviral, anti-malarials and anti-tuberculosis drug production — is insufficient to ensure an adequate supply and access to all essential medicines for all Tanzanians. Drug stock-outs are common in Tanzanian health facilities, distribution is inadequately monitored, and it is quite possible that medicines intended for free distribution in the public sector are leaking onto the black market. As a result of drug stock-outs at public facilities, many Tanzanians pay out-of pocket to retail pharmacists in order to access medicines, frequently impoverishing themselves further in the process.

Strengthening the pharmaceutical sector to produce an adequate supply of medicines in Tanzania, for Tanzanians, is also hindered by numerous constraints, including:

- Since Trade Related Intellectual Property Rights' (TRIPS) flexibilities are not included in Tanzanian law, the range of generics local pharmaceutical manufacturers can produce is limited;
- Lack of skilled staff;
- Financial constraints (most donors are not interested in developing the pharmaceutical sector; most investors prefer to invest in purely private companies — not PPPs; and borrowing from local banks is expensive);
- Poor industrial infrastructure and services, leading to high operating costs;
- Weak local and international pharmaceutical industry links; and
- Counterfeit medicines entering the market.

Therefore, the Ministry of Health and Social Welfare must urgently step up its own monitoring systems — both for GMP and for ensuring effective distribution of medicines to health facilities. New legislation is also needed to improve quality standards, implement TRIPS flexibilities in Tanzanian law, and tackle harmful counterfeit medicines entering the market. Systems and facilities must also be put in place to skill Tanzanians to ensure:

- Skilled staff are available for medicine manufacturing;
- Financing facilities for drug manufacturers are adequate, more effective and streamlined; and
- Industrial zones are created where manufacturers (not just in the pharmaceutical sector) can access quality infrastructure and services so as to reduce operating costs and make existing pharmaceutical production more viable.

2. c. National supply, storage and distribution systems

Yadav, P. 2007, *Analysis of the Public, Private and Mission Sector Supply Chains for Essential Drugs in Zambia*, DFID Health Resource Centre.

http://www.medicines Transparency.org/fileadmin/uploads/Documents/countries/Supply_Chain_Reports/MeTA_Zambia_Supply_Chain_Report.pdf

This report provides an overview of the different players, their roles and functions within the public sector, the private sector and the mission sector supply chain for medicines in Zambia. Transparent and institutionally strong pharmaceutical supply chains can strongly contribute towards improving access to essential drugs. However, pharmaceutical supply and distribution systems in most countries are often a complex network of heterogeneous stakeholders from the public, private-for-profit and private-non-profit sectors.

Nakyanzi, J. K. Et al. 2010. Expiry of medicines in supply outlets in Uganda. *Bull World Health Organ*; 88:154–158

<http://www.who.int/bulletin/volumes/88/2/08-057471.pdf>

The expiry of medicines in the supply chain is a serious threat to the already constrained access to medicines in developing countries. This paper details an investigation into the extent of, and the main contributing factors to, expiry of medicines in medicine supply outlets in Kampala and Entebbe, Uganda. A cross-sectional survey of six public and 32 private medicine outlets was done using semi-structured questionnaires. The study area has 19 public medicine outlets (three non-profit wholesalers, 16 hospital stores/pharmacies), 123 private wholesale pharmacies and 173 retail pharmacies, equivalent to about 70% of the country's pharmaceutical businesses. The findings indicate that medicines prone to expiry include those used for vertical programmes, donated medicines and those with a slow turnover.

It was found that awareness about the threat of expiry of medicines to the delivery of health services has increased. Training modules have been adapted to emphasize management of medicine expiry for pharmacy students, pharmacists and other persons handling medicines.

Poor coordination appears to be responsible for some expiry incidents. For example, expiry due to treatment policy change and duplicate procurement can be prevented by sound coordination between key stakeholders. Even though a medicine procurement and supply management task force was set up by Uganda's Ministry of Health to plan the phasing out of chloroquine and sulfadoxine/pyrimethamine, the expiry of large stocks of the latter suggests a serious lapse in coordination. Countries undertaking similar ventures should involve their national medicine regulatory agencies at all stages of the transition process to guide local production and to curtail entry of phased-out medicines into the market well before implementation of the change. Furthermore, rigorous coordination between suppliers and their clients is critical to the success of the "pull" system of supply of medicines used by Uganda's National Medical Stores, as it ensures that the supplier's forecasted turnover keeps in harmony with the consumption of its clients.

Similarly, better coordination between government projects or vertical programmes and public medical stores can ameliorate the problem of overstocking associated with duplicate procurement, as well as harmonise medicine quantification with prescribing habits and preferences of consumers to ensure procurement matches turnover. This can be achieved with the involvement of prescribers in determining the scope and quantities of supplies, and the use of surveys of consumer tastes and preferences to determine suitable dosage forms for example.

Medicines with slow and unpredictable turnover are generally prone to expiry. The standard approach of ordering economic quantities to optimize stock levels only works for medicines with stable consumption and is inappropriate for those with erratic demand. Rigorous vigilance in inventory management and maintenance of minimum stock levels is the best approach to reduce expiry of these medicines. Although robust international guidelines for donation of medicines have been in existence since 1996, national medicine regulatory authorities need to take control and enforce them in their own country. Pharmaco-economists favour bulk purchasing for economies of scale, but this can lead to overstocking and thus exacerbate expiry. This can however be mitigated by appropriate procurement phasing, lean supply and stock rotation. A lean supply policy would specifically prevent expiry of items with a short shelf-life, though its effectiveness requires a robust logistics management information system.

It was found that expiry of medicines is a systemic barrier to access to medicines. Sound coordination is needed between public medicine wholesalers and their clients to harmonise procurement and consumption as well as with vertical programmes to prevent duplicate procurement. Additionally, national medicine regulatory authorities should enforce existing international guidelines to prevent dumping of donated medicine.

Jitta, J. Et al. The availability of drugs: what does it mean in Ugandan primary care. 2003, *Health Policy*; 65

<http://docs.mak.ac.ug/sites/default/files/Health%20Systems.pdf>

Availability of drugs is often considered the most important element in quality of health care in rural African settings. Using material collected through mainly qualitative methods, this article examines drug availability in six primary health care units in south eastern Uganda. Emphasis is on the differing perspectives of three categories of actors: health planners/managers; health workers; and users of health services. The main concern is the availability of chloroquine and penicillin, especially injectable forms, and the needles and syringes for administering them. Health sector reforms have changed the conditions for managing, supplying, and using drugs through decentralisation, user fees, and privatisation. Patients were dissatisfied when they were not able to obtain all drugs prescribed at the health unit. Government health units both compete with, and use, local commercial sources of drugs. They need to attract patients and, with user fees, they are more able to supplement the drug

kit supplies provided through the Ministry of Health. There is a need to revise policy in light of the new situation. Dialogue and realism are needed in order to create policies that respect both good medical treatment standards and the concerns of frontline workers and their patients. The exercise of rethinking the meaning of drug availability in primary health care calls for methodologies examining the changing context of health care and the positions of different categories of actors, at national and district setting, to appreciate gaps existing between drug policy and practice.

2. d. Human resource capacity

Steyn, F. Et al. 2009, Scaling up access to antiretroviral drugs in a middle-income country: public sector drug delivery in the Free State, South Africa. *AIDS Care*; 21 (1)
<http://www.ncbi.nlm.nih.gov/pubmed/19085214>

This article describes the distribution and management of drugs and supplies in scaling up access to public sector antiretroviral treatment (ART) in a middle-income country. More specifically, a case study of the Free State Province of South Africa is presented focusing on: the mobilisation and training of pharmaceutical staff for ART, processes related to the ordering, distribution and storage of medicines, continuity of ART supplies and the impact of ART delivery on other drugs and supplies. Data were obtained from longitudinal research conducted between April 2004 and July 2006 comprising three surveys of the first 20 health facilities providing ART in the province, key informant interviews and observations made of provincial ART Task Team meetings.

The supply of ART in the Province was managed through the existing drug supply system but with special mechanisms to ensure integrity of ART supplies and security of stock within the existing supply system. Initial hiccups in the procurement of antiretroviral (ARV) drugs for South Africa (a national function) caused delays in putting patients on ART, although these supply problems were short-lived. At provincial level, not all pharmacist posts created for the programme were filled, and pharmacists working in the rest of the health system were subsequently trained to take on ART programme functions. Electronic systems were not established at all service sites, which in part contributed to delays in the delivery of drugs and supplies to more peripheral units. Adequate space to safely store ARV drugs remained problematic. The introduction of the ART programme did not create disruptions in the supply of non-ART essential drugs, which in fact improved over the period of observation.

It is concluded that despite some process, human resource and infrastructural challenges, the drug management system in the Free State succeeded in incorporating public sector ART within its existing drug distribution network and functions, at least in the initial phase of scale up.

Schneider, H. Et al. 2006, Health Systems and Access to Antiretroviral Drugs for HIV in Southern Africa: Service Delivery and Human Resources Challenges. *Reproductive Health Matters* 2006; 14 (27):12–23
<http://www.ncbi.nlm.nih.gov/pubmed/16713875>

Without strengthened health systems, significant access to antiretroviral (ARV) therapy in many developing countries is unlikely to be achieved. This paper reflects on systemic challenges to scaling up ARV access in countries with both massive epidemics and weak health systems. It draws on the authors' experience in southern Africa and the World Health Organization's framework on health system performance.

Whilst acknowledging the still significant gap in financing, the paper focuses on the challenges of reorienting service delivery towards chronic disease care and the human resource crisis in health systems. Inadequate supply, poor distribution, low remuneration and accelerated migration of skilled health workers are increasingly regarded as key systems

constraints to scaling up of HIV treatment. Problems, however, go beyond the issue of numbers to include productivity and cultures of service delivery. As more countries receive funds for antiretroviral access programmes, strong national stewardship of these programmes becomes increasingly necessary.

The paper proposes a set of short- and long-term stewardship tasks, which include resisting the 'verticalisation' of HIV treatment, the evaluation of community health workers and their potential role in HIV treatment access, international action on the brain drain, and greater investment in national human resource functions of planning, production, remuneration and management.

There is growing consensus that a long-term perspective on ARV scale-up has to address the critical shortage of human resources. This would include at a minimum:

- Promoting international action on the brain drain;
- At country level (re)investment in traditional human resource functions such as planning, production, remuneration and management of health care providers;
- Addressing macro-economic constraints on employment and remuneration of health care providers;
- Evaluation of the performance of existing nationally developed cadres such as mid-level and community health workers and their potential role in HIV treatment scale-up.

2. e. Facility level ordering, storage and distribution systems

Carasso, B. et al. 2009 Availability of essential medicines in Ethiopia: an efficiency-equity trade-off? *Tropical Medicine and International Health*; 14 (11)

<http://onlinelibrary.wiley.com/doi/10.1111/j.1365-3156.2009.02383.x/full>

This paper aims to investigate the availability and cost of essential medicines in health centres in rural Ethiopia, and to explore if the fee waiver system protects patients from having to pay for medicines. The results indicate that the availability based on essential drugs at facility level was 91% based on a list of selected drugs vs. 84% based on prescriptions filled. However, less than half the prescribed drugs were obtained from the budget pharmacy, and one in six patients was forced to purchase drugs in the private sector, where drugs are roughly twice as expensive. The waiver system did not safeguard against having to pay for medicines. The study concludes that a revolving drug fund system in Ethiopia seems to improve availability of medicines, and can improve affordability by protecting people from purchasing drugs in the private sector. However, it may result in a parallel system, whereby the poor cannot access drugs if these are not available in the budget pharmacy. Equity is a concern in the absence of an adequate mechanism to protect the poor from catastrophic health expenditure. At the facility level, it is clear that a strengthened supply chain system, proper stock management by qualified staff and sufficient budget for drug procurement will also improve availability of medicines.

Lufesi, N. Et al. 2007, Deficient supplies of drugs for life threatening diseases in an African community, *BMC Health Services Research*; 7 (86)

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1906855/>

This paper focuses on essential medicine in Malawi. It was found that in Malawi essential drugs are provided free of charge to patients at all public health facilities in order to ensure equitable access to health care. The country spends about 30% of the national health budget on drugs. To find the reasons for the drugs shortages in Malawi, the management of the drug supplies for common and life threatening diseases such as pneumonia and malaria in a random selection of health centres were studied. 37 health centres were chosen at random in the Lilongwe District, Malawi. The authors recorded the logistics of eight essential and widely

used drugs which according to the treatment guidelines should be available at all health centres. Five drugs are used regularly to treat pneumonia and three others to treat acute malaria. Out-of-stock situations in the course of one year were recorded retrospectively. The quantity of each drug recorded on the Stock Cards was compared with the actual stock of the drug on the shelves at the time of audit. 8,968 Patient Records were reviewed, which contained information on type and amount of drugs prescribed during one month.

The results indicate that on average, drugs for treating pneumonia were out of stock for six months during one year of observation (median value 167 days); anti-malarial drugs were lacking for periods ranging from 42 to 138 days. The cross-sectional audit was even more negative, but here too the situation was more positive for anti-malarial drugs. The main reason for the shortage of drugs was insufficient deliveries from the Regional Medical Store. Benzyl penicillin was in shortest supply (4% received). The median value for non-availability was 240 days in the course of a year. The supply was better for anti-malarial drugs, except for quinine injections (9 %). Only 66 % of Stock Card records of quantities received were reflected in Patient Records showing quantities dispensed.

It was concluded that for the eight index drugs the levels of supply are unacceptable. The main reason for the observed shortage of drugs at the health centres was insufficient deliveries from the Regional Medical Store. A difference between the information recorded on the Stock Cards at the health centres and that recorded in the Patient Records may have contributed to the overall poor drug supply situation. In order to ensure equitable access to life saving drugs, logistics in general should be put in order before specific disease management programmes are initiated.

2. f. Patents

Ashcroft, R. 2005, Access to essential medicines: a Hobbesian social contract approach. *Developing World Bioethics*, 5 (2)

<http://onlinelibrary.wiley.com/doi/10.1111/j.1471-8847.2005.00108.x/abstract>

This paper argues in support of states' sovereign right to expropriate private intellectual property in conditions of public health emergency. This argument turns on a social contract argument for the legitimacy of states. For many serious diseases (such as HIV/AIDS and tuberculosis) essential medicines are protected by patents that permit the patent-holder to operate a monopoly on their manufacture and supply, and to price these medicines well above marginal cost. The argument shows that under some circumstances states are not merely permitted compulsory to license inventions, but are actually obliged to do so, on pain of failure of their legitimacy as sovereign states. The argument draws freely on a loose interpretation of Thomas Hobbes's arguments in his *Leviathan*, and on an analogy between his state of War and the situation of public health disasters.

Durojaye. E. 2008, Compulsory licensing and access to medicines in post Doha era: what hope for Africa? *Netherlands International Law Review*, LV: 33-71

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1528602

This article examines the importance of compulsory licensing, with a focus on human rights, to facilitate access to life-saving medications for Africans and its use after the historic decision at Doha in 2001 (popularly called 'Doha Declaration'). The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of 1994, an outcome of the Uruguay Round negotiations, radically altered the role of international trade law in promoting and enforcing intellectual property protection around the globe. This paper discusses the August 2003 Decision of the Council for TRIPS and the subsequent December 2005 amendment of the TRIPS Agreement in an attempt to resolve paragraph 6 of Doha Declaration. It submits that both are neither faithful to the spirit of Doha nor are they in line with provisions of human rights instruments, which guarantee the rights to health and life. Also, the article reasons that

recent developments in the world on the use of compulsory licensing, such as the new Canadian legislation on this issue, have not in any way brought succour to Africans. The article further argues that in view of the above situations, particularly the failure of both the August 2003 Decision of the Council for TRIPS and its amendment of the TRIPS Agreement to find a lasting solution to the unresolved paragraph 6 of Doha, African countries may need to be creative in invoking other provisions of the TRIPS such as Article 31(k) so as to ensure affordable medicines for their citizens. The article then considers the likely tension that may exist between human rights and intellectual property rights, and submits that the obligations of states under the former should supersede the latter.

It concludes that it is of great concern, that the Declaration at Doha is being undermined by the negative attitudes of developed countries to the use of compulsory licensing. This is prejudicial to the interest of Africans who are in dire need of life-saving medications. It may be contended that developed countries and pharmaceutical companies both have the duty under international law to ensure that their actions do not by any means hinder access to medicines for those in poor countries of the world.

Bird, R. 2009, Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects. *Journal of law, medicine & ethics*; 37 (2)

<http://onlinelibrary.wiley.com/doi/10.1111/j.1748-720X.2009.00366.x/abstract>

This paper addresses how developing countries can maximise access to essential medicines and minimise unwanted side effects within the legal environment of a compulsory license regime. It offers various solutions that developing nations can implement to improve consumer access without costly expenditures or foreign aid. This paper concludes that, while compulsory licensing can play a role in improving public health, external social and political conditions must be considered in order to make licensing an effective practice.

Compulsory licensing is a potentially powerful tool that developing nations can use to circumvent patent laws and give their residents access to life-saving medicines. The problem with compulsory licenses is that they provoke unintended reactions from patent holders and cause nations to suffer unintended economic consequences. Too often, licenses are derailed into trade protection measures for local interests. Most importantly, such licenses may not achieve their intended purpose — to improve access of pharmaceutical drugs to low-cost consumers. Developing countries must not issue licenses without considering potential consequences. Licensing statutes must not be overly broad and should be drafted in consultation with the affected patent holders. The problem of drug access is not only a legal but moral issue that can shape public opinion and nations should use that to their advantage. Nations must make a concerted effort to alleviate suspicion of Western drugs and improve their infrastructures that regulate how these drugs are distributed. If a nation must issue a compulsory license, it must do so in a fashion that genuinely conveys a commitment to improving public health. Further dialogue is needed to explore the ways in which developing countries can control their own destinies within the confines of their limited resources.

- Consumer education about the risks of counterfeit drugs, prevalent in developing nations, can reduce the risk of illness or death from consuming inert or harmful compounds posing as the genuine medicine.
- Nations can also cooperate through collective bargaining to pool their economic strength and extract more favourable prices from patent owners. The role of corruption and illegal parallel importation in impeding access to drugs has yet to be fully explored. Further study could contribute much to the literature in understanding how developing nations can control their own public health destiny.
- Every year, millions die needlessly from maladies which can be treated or cured with available medicines.

- While compulsory licenses can play a role, their issuance alone cannot solve the drug access problem.
- Although many parties play a role in influencing the dissemination of drugs, government representatives can take matters in their own hands to make access to life-affecting medicines as uncomplicated as possible.

Ravvin, M. 2008, Incentivizing Access and Innovation for Essential Medicines: A Survey of the Problem and Proposed Solutions. *Public health ethics*; 1 (2)
<http://phe.oxfordjournals.org/content/1/2/110.short>

The existing intellectual property regime discourages the innovation of, and access to, essential medicines for the poor in developing countries. A successful proposal to reform the existing system must address these challenges of access and innovation. This essay surveys the problems in the existing pharmaceutical patent system and offer critical analysis of some reform proposals. It argues that existing mechanisms that are intended to mitigate the harms of the current pharmaceutical patent system, such as bulk buying, differential pricing and compulsory licenses, are inadequate and perhaps even counter-productive over the long-term. Other incentive mechanisms based on push funding, such as government research grants, are inefficient and limited in scope. Pull mechanisms, which offer some reward for successful pharmaceutical innovations, offer a more promising incentive mechanism. Three pull mechanisms are evaluated – Priority Review Vouchers, Advance Market Commitment (AMC) and the Health Impact Fund – on the basis of their capacity to incentivise access and innovation, as well as their efficiency and political feasibility. Though the Health Impact Fund appears to be the most promising proposal, more work must be done to overcome challenges of its implementation.

The paper concludes that the pharmaceutical patent system has contributed significantly to a global health crisis that continues to deteriorate. Because this crisis is partially the result of policies instituted primarily by affluent countries, and results in so much avoidable human suffering, we have a strong moral duty to seek alternatives. Any successful reform of the current system must increase access to essential medicines among the poor and incentivise innovation of new medicines for diseases that predominantly afflict developing countries. So long as the existing patent system links rewards for innovation only to the price system, a solution to this crisis is unlikely to be found. However, it is possible to create a mechanism that will reward innovative firms based on the actual health impact of their innovations, rather than the high prices that patented drugs can fetch. To succeed, such a mechanism must expand access and innovation, but it must also be efficient, sustainable and politically feasible. The best option for achieving these goals appears to be the Health Impact Fund. It is hoped that further development of this proposal will yield a viable and successful complement to the existing pharmaceutical patent system.

3. Additional information

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