

What If a Quarter of a Loaf Is Not Much Better Than None? The Role of the Social Health Insurance Scheme in Promoting Access to Medicines in Ethiopia - An Overview

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Abstract

Hundreds of millions of people worldwide do not have access to essential medicines, particularly in Africa and many parts of Asia, and hence, millions of people avoidably die every year. Moreover, as people in these countries pay for their own medicines, the expenditure on medicines coupled with their high prices is pushing people to poverty. This forces us to see enhancing access to medicines by all means as not only a major component in realizing the right to health/life, but also as a tool in contributing its share in the fight against poverty. One of the means through which access to medicines may be enhanced and out-of-pocket spending may be avoided is by introducing health insurance schemes with medicines forming part of the benefit package. Proclamation No. 690/2010 establishes a Social Health Insurance Scheme in Ethiopia, which contains medicines as one of the benefits of the scheme. Although it suffers from certain shortcomings, the system is a commendable step in enhancing access to medicines for its beneficiaries. This article looks into some of the major shortcomings of the scheme, and tries to assess the role of donors, pharmaceutical companies and NGOs in terms of enhancing the formulary and accordingly improve access to medicines to the beneficiaries of the scheme.

Key Words:

[Social] health insurance schemes, access to medicines, generic drugs/medicines, pharmaceutical companies, out-of-pocket spending

Introduction

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The right to health is one of the fundamental rights in both international and domestic human rights instruments. The fact on the ground, however, and particularly in developing and least developed countries, leaves much to be desired. States have the primary responsibility to see it to that all the necessary measures are taken to ensure the realization of the right, most notably by bringing health care services within the reach of their citizens. However, as states are not delivering, millions of people continue to die every year across the globe either due to lack of, among other things, basic health services and/or medicines.

Needless to say, medicines play a significant role in realizing the right to health. However, one-third of the world's population lacks access to the most basic essential drugs and, in the poorest parts of Africa and Asia, this figure climbs to one half.⁹⁴ A World Health Organization (WHO) estimate shows that ten million people die every year because of lack of access to medicines.⁹⁵ The reason for this lack of access to medicines may vary. Poverty, national laws and international agreements such as the TRIPS Agreement, which requires that pharmaceuticals are to enjoy a minimum of twenty years patent protection, are some of the important reasons for the access gap in most countries. Patent on pharmaceuticals, whose prices may go as high as ten thousand percent as compared with their generic counterparts, is often justified as a means to enable the pharmaceutical companies recover their expenses on their R&D. Indeed, some drugs take years and cost millions of dollars before they are put on the market. However, according to the Fortune 500, the pharmaceutical industry remains by far the most profitable in the world, well ahead of companies in all other sectors, and that profits far exceed what is necessary for a "reasonable" return on their R&D.⁹⁶ Be that as it may, while brand medicines are obviously not affordable for the poor, pharmaceuticals

⁹⁴ Ellen F. M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' (2003) p.42

<www.who.int/intellectualproperty/topics/ip/tHoen.pdf>' accessed 17 July 2013'.

⁹⁵ 'Equitable Access to Essential Medicines: A Framework for Collective Action', World Health Organization, (2004) Geneva

<http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf>' accessed 17 July 2013'.

⁹⁶ See "The 2002 Fortune 500". Fortune Magazine, April 2002, in Richard Elliott and Marie-Hélène Bonin, 'Patents, International Trade Law and Access to Essential Medicines' Medecins Sans Frontieres (2002)

<www.umich.edu/~spp638/Coursepack/ipr-msf.pdf>' accessed 4 November 2013'.

produced since 1994 are protected, out of which no generic drugs may be produced, save in certain exceptional circumstances.

Given most essential drugs are not affordable and in most cases not available, states need to seek ways to enhance access to medicines. One such way is introducing health insurance schemes with a view to pooling risks, which may relieve members of the scheme from out-of-pocket spending on medicines and also ensure, to some extent, their availability. Although, a number of insurance companies have had private insurance schemes for a couple of years now, the introduction of social health insurance scheme in Ethiopia is a fairly new experience. The Ethiopian social health insurance scheme covers employees and pensioners (and their families) as beneficiaries of the system, where a number of health care services are available, including medicines. The fact that the social health insurance scheme incorporates medicines as part of its benefit, regardless of the shortcomings, inspires optimism in ensuring access to medicines for the portion of the population covered by the system.

The main objective of the article is to bring the Ethiopian health insurance scheme to light and its role in enhancing access to medicines. In doing so, it attempts to discuss some of the shortcomings of the scheme and opportunities available. The other objective of the article is to lay a foundation for future research and dialogue on health insurance and access to medicines.

The article is divided into four sections. This short introduction is followed by an overview of health insurance schemes and some of the major challenges on access to medicines. The second section, by starting with an introduction of the Ethiopian social health insurance scheme, goes on to briefly highlight the contributions of the system in terms of ensuring access to medicines. Section three examines some of the shortcomings of the social health insurance scheme. The last section explores the roles of donors, pharmaceutical companies and NGOs in helping the Agency possess a well off depository and bringing the beneficiaries of the system a step closer to essential medicines.

It should be noted that the author's persistent requests to get information from the Agency were repeatedly rejected, even after producing a support letter from the Center upon the request of the Deputy Director of the Agency himself. Failure to acquire the necessary information from the Agency has seriously impacted on the outcome of the piece. The article, therefore, chiefly relies on survey of literature and analysis of the Social

Health Insurance Scheme Proclamation and Regulations and other relevant laws.

1. [Social] Health Insurance Schemes and Access to Medicines

1.1. [Social] Health Insurance Schemes

Health insurance is a mechanism for spreading the risks of potential health care costs over a group of individuals or households, with the goal of protecting the individual from a catastrophic financial loss in the event of serious illness.⁹⁷ The system is designed in such a way that its beneficiaries are relieved from out-of-pocket expenses in respect of the health service packages the insurance covers. Hence, health insurance is attracting more and more attention in low- and middle-income countries as a means for improving health care utilization and protecting households against impoverishment from out-of-pocket expenditures.⁹⁸

A number of health insurance models exist worldwide. Among these, the following are common:

Private Health Insurance refers to schemes that are financed through private health premiums, which are usually (but not always) voluntary.⁹⁹ As private health insurance is provided by private entities, the money can be paid directly to the insurance company.¹⁰⁰ Because of its characteristics, most notably high premiums, private health insurance is out of the reach of the poor.

Community-based health insurance schemes (mutuelles de santé) are voluntary, not-for-profit health insurance schemes organized at a

⁹⁷ John Chalker, 'Pharmaceutical Benefits in Insurance Programs' in Management Sciences for Health. MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: (2012)
<<http://apps.who.int/medicinedocs/documents/s19588en/s19588en.pdf>>
'accessed 29 October 2013'.

⁹⁸ 'The impact of health insurance in Africa and Asia: a systemic review', Bulletin of the World Health Organization (13 June 2012)
<www.who.int/bulletin/volumes/90/9/12-102301/en/> 'accessed 28 August 2013'.

⁹⁹ Chalker (n 4 above) p.14.

¹⁰⁰ *ibid.*

community level that specifically target those outside the formal sector.¹⁰¹ Common in most developing and least developed countries, this kind of insurance is introduced to cover populations that live in rural areas and work in informal sectors.¹⁰²

Social Health Insurance is a kind of health insurance where a designated group of the population is included.¹⁰³ Key features of a successful social insurance plan include:

- compulsory or mandatory membership;
- prepayment contributions from payroll deductions based on income;
- cross-subsidization and coverage of a large proportion of the population;
- benefit based on need;
- arrangement of social assistance to cover vulnerable populations;
- collected revenue administered by a quasi-independent body.¹⁰⁴

Hence, social health insurance schemes are generally understood as health insurance schemes provided by governments to their citizens, especially to low and middle income populations.¹⁰⁵ At this juncture, it is important to differentiate social health insurance from 'tax based financing' where the latter typically entitles all citizens (and sometimes residents) to services thereby giving universal coverage.¹⁰⁶ In other words, membership to a social health insurance scheme is reserved for certain portions of the

¹⁰¹ Ceri Averill, 'Universal Health Coverage: Why health insurance schemes are leaving the poor behind' (2013) p.9
<www.oxfam.org/sites/www.oxfam.org/files/bp176-universal-health-coverage-091013-en_pdf> 'accessed 6 November 2013'.

¹⁰² Chalker (n 4 above) p.12.

¹⁰³ *ibid*, p.11.

¹⁰⁴ *ibid*.

¹⁰⁵ Arnab Acharya et al, 'Do Social health insurance schemes in developing country settings improve health outcomes and reduce the impoverishing effect of healthcare payments for the poorest people?' Cochrane Database of Systematic Reviews, p.2
<<http://r4d.dfid.gov.uk/PDF/Outputs/SystematicReviews/FINAL-Q40-Social-Health-Insurance-Protocol-DFID-LSHTM.pdf>> 'accessed 28 August 2013'.

¹⁰⁶ *ibid*, p.3.

population as stipulated in the particular social health insurance scheme concerned.

Social health insurance schemes are gaining much attention, both in national systems and at the international level, as a viable option to finance health care needs of the public, particularly the poor. The WHO in 2005 passed a resolution that it would support a strategy to mobilize more resources for health, for risk pooling, increase access to health care for the poor and deliver quality health care in all its member states but especially low income countries.¹⁰⁷ This strategy is also supported by the World Bank.¹⁰⁸

1.2. Access to Medicines and its Challenges

As guaranteed and reiterated by the major human rights instruments across the globe, both international¹⁰⁹ and municipal,¹¹⁰ the right to health of people is a very important right in the human rights discourse. The realization of the right has, however, proved rather difficult to come by, particularly in Africa and many parts of Asia as well as in other poor parts of the world. The poor health condition in these parts of the world is further exacerbated by the lack of access to medicines, as medicines play an enormous role in the realization of the right.¹¹¹

¹⁰⁷ WHO Sustainable Health Financing, Universal Coverage, and Social Health Insurance in 58th World Health Assembly Agenda Item 13.16 Edition Geneva, 2005, in Acharya et al. (n 12 above) p.2.

¹⁰⁸ Hsiao W, Shaw RP, 'Social Health Insurance for Developing Nations', The World Bank Washington, D.C. 2007 in Acharya et al. (n 12 above) p.2.

¹⁰⁹ International human rights instruments that guarantee the right to health include the UDHR (Article 25), ICESCR (Article 12 See also the Economic Social and Cultural Rights General Comment 14), CEDAW (Article 12), ACHPR (Article 16 See also ACHPR Res. 141), Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (Article 14).

¹¹⁰ According to Pehudoff, by 2009, 135 countries had incorporated aspects of the right to health in their national constitutions. See S.K Pehudoff, 'Health, Essential Medicines, Human Rights and National Constitutions', Geneva, WHO in Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade (2008) <www.who.int/medicines/areas/human_rights/Pehudoff_report_constitutions_2008.pdf> 'accessed 27 April 2012'.

¹¹¹ As has been said above, in the poorest parts of Africa and Asia, about half of the population lack access to the most basic essential drugs.

The situation becomes unthinkable if one considers the United Nations Development Group's definition of access, i.e. having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population.¹¹² Yet, in the majority of places in the developing countries, which gets worse in the least developed ones, the practicability of this definition is not in sight and remains a mere desire.

Both the availability and price of medicines are beyond the reach of the majority of the people in developing and least developed countries. One can come up with a number of factors that stand in the way of access to medicines in these countries. In addition to the factors mentioned above, such factors include lack of equity in the supply of essential medicines, high prices, informal payments and out-of-pocket payments for the medication required exclude the poor and vulnerable, and do not facilitate the realization of the right to health.¹¹³

Among the factors mentioned above, poverty, coupled with the high cost of medicines is one of the biggest challenges. Pfizer's study shows that approximately 4 billion people, 72 percent of the world's population, live on less than three dollars a day, of which, between 50 to 90 percent of annual total health care expenditures by the world's poorest people, approximately \$30 billion annually, goes to pay for medicines.¹¹⁴ Moreover, Leisinger et al. study shows that average availability of generic medicines is only 38 percent in the public sector in low- and middle-income countries, and, although private sector availability is higher – on average 64 percent – medicines in private pharmacies are often not affordable.¹¹⁵

¹¹² United Nations Development Group, Indicators for Monitoring the Millennium Development Goals: Definitions, Rationale, Concepts and Sources p.81 (United Nations, New York, 2003).

¹¹³ See Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade WTO, WHO, WIPO <www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm> 'accessed 18 October 2013'.

¹¹⁴ Pfizer, Access to Medicines, 2009 Corporate Responsibility Report, p.29 <www.pfizer.com/files/corporate_citizenship/cr_report/access_meds.pdf> 'accessed 31 October 2014'.

¹¹⁵ KM Leisinger, et al, Improving Access to Medicines in Low and Middle Income Countries: Corporate Responsibilities in Context. Southern Med Review Vol 5, Issue 2; (2012) p.3.

Lack of R&D in developing countries is also another problem. A number of justifications may be raised for the lack of involvement in R&D in pharmaceuticals in these countries. Lack of the necessary fund to undertake the tedious R&D in pharmaceuticals is one justification, as it sometimes takes hundreds of million dollars and years to develop a certain drug. The problem of lack of R&D in such countries is magnified by the fact that many research based pharmaceutical companies in most cases are profit oriented and thus not interested in developing medicines essential for the poor living in these parts of the world.¹¹⁶ This and many other reasons force us to see the issue as an injustice to the poor.¹¹⁷

The other important challenge on access to medicines is the WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPS).¹¹⁸ The TRIPS Agreement, which was born out of the Uruguay Round of Negotiations and forms part of WTO's single undertakings,¹¹⁹ brought about minimum standards for the protection of intellectual property, including patents on pharmaceuticals. While incorporating an agreement on intellectual property amid the existence of other international

¹¹⁶ This should not be taken to mean that pharmaceutical companies are not wary of the lack of access to medicines of the poor. As Section 4.2 below illustrates, many pharmaceutical companies have been engaged in donating, even developing certain drugs for the needs of the poor in Africa and other parts of the world.

¹¹⁷ Yamin, for example, states that "viewing access to medicines as a matter of fundamental human rights forces us to face the momentous suffering and loss of life that is occurring in developing countries due to HIV/AIDS, tuberculosis, malaria, and other diseases as not just a tragedy; it forces us to recognize it as a horrific injustice". See Alicia Yamin, 'Not Just a Tragedy: Access to Medications as a Right under International Law', Boston University International Law Journal, Vol. 21:325, (2006) p.370.

¹¹⁸ The basic objective of the TRIPS Agreement is to give adequate and effective protection to intellectual property rights, so that the owners of these rights receive the benefits of their creativity and inventiveness, and are thereby also encouraged to continue their efforts to create and invent. The TRIPS Agreement covers copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, undisclosed information.

¹¹⁹ As can be seen from the Annex to the WTO Agreement containing the different Agreements, Annex I contains the multilateral agreements on Trade in Goods, Services and Intellectual Property. As a country cannot opt to sign one and reject others from these Multilateral Agreements, they are commonly referred to as single undertakings. Such an option, however, is available in the Plurilateral Agreements, found under Annex IV of the Agreement.

agreements¹²⁰raised many eyebrows by itself, TRIPS required WTO members to offer patents on pharmaceuticals for the first time under the intellectual property protection regime. Article 27 provides that ‘patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application’. Members are, therefore, required to amend or adopt patent laws incorporating the minimum standards set forth in the TRIPS. Regardless of the flexibilities under the TRIPS Agreement and some other options outside the TRIPS, the Agreement is bad news for the majority of the poor worldwide, for whom medicines keep going in the other direction.

As an importer of generic medicines, Ethiopia will be one of the countries highly affected by the TRIPS Agreement.¹²¹As will be discussed in the subsequent sections, in the absence of a strong and an all-inclusive health insurance schemes in Ethiopia, this is bad news for the majority of

¹²⁰ Prior to the TRIPS Agreement, the Paris Convention was the main international instrument governing patents at the international level but it contains few binding rules. There was for example no obligation to make available patents for any particular technology; nor was there a set of exclusive rights to be conferred on patent holders. There was also no minimum term of protection prescribed by the Paris Convention. Indeed, several countries used to exclude pharmaceutical products and processes from patent protection and preserved different patent policy that fit into their socioeconomic needs. See Fikremarkos Merso, ‘Ethiopia’s Accession to the WTO: Does It Imply Anything on Access to Affordable Medicines in Ethiopia? In Fikremarkos Merso (ed) ‘WTO Accession: Assessing the Benefits and Costs for Ethiopia’, Ethiopian Business Law Series, Vol. 2 157 (2008) p.163.

¹²¹ It is worth noting that as a generic importer (mostly from India), the impacts of the TRIPS Agreement on access to medicines in Ethiopia will be significant even if Ethiopia stays out of the WTO. As Fikremarkos rightly notes, “until recently, drug importing countries like Ethiopia have the option of importing supplies from generic companies, principally in India, because India did not recognise patents for pharmaceutical products until the time when the TRIPS Agreement came into force and even after the coming into force of the TRIPS Agreement the country was given a transition period (of five years) until 2005 to implement the Agreement. In 2005, India introduced a new patent law in compliance with the TRIPS Agreement where new drugs and those for which patent applications were submitted after 1994 have become patentable, and as a result the opportunity for generic imports will likely diminish gradually”. See Fikremarkos (n 27 above) pp.169-170. The same holds true as the other prominent generic producing companies are found in China, Brazil, South Africa, which are members of the WTO.

Ethiopians where health services and medicines form part of out-of-pocket expenses.¹²² To make matters worse, a considerable number of the population is dying from communicable diseases such as HIV/AIDS and TB, as well as non-communicable diseases such as hypertension, diabetes and heart disease. This certainly distorts Ethiopia's efforts towards the realization of the right to health of the people envisaged in the FDRE Constitution, as well as the human rights instruments of universal and regional application to which Ethiopia is a party.

2. The Ethiopian Social Health Insurance Scheme

2.1. An Overview of the Ethiopian Social Health Insurance Scheme

Proclamation No. 690/2010 (Proclamation) establishes a social health insurance scheme.¹²³ As with the objectives of social health insurance scheme in most systems, the objective of the social health insurance is to 'provide quality and sustainable universal health care coverage to the beneficiary through pooling of risks and reducing financial barriers at the point of service delivery'.¹²⁴ The Proclamation further provides that it does not affect additional medical benefits granted under collective agreements concluded in accordance with the Labour Proclamation No. 377/2003 and additional medical benefits granted by police health institutions to members of the police.

Pursuant to Article 6 of the Proclamation, members' and employers' contributions, investment income and other related sources are the sources of finance of the social health insurance. Although some systems do not

¹²² The exception in this regard is the existence of public hospitals and health institutions which offer health services at low cost, which play a significant role in cutting expenditures on health services. Watal notes that expenditures on medicines can represent up to 66% of total health spending in developing countries and could be a major cause of household impoverishment, as 50-90% of such expenditures are out-of-pocket expenses. Jayashree Watal, 'Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?' Science, Technology and Innovation Discussion Paper No. 8, (2000) Center for International Development, Harvard University. <www.cid.harvard.edu/archive/biotech/papers/discussion8.pdf> 'accessed 9 March 2012'.

¹²³ Social Health Insurance Proclamation No. 690/2010, 16th Year, No. 50 (2010) *Federal Negarit Gazeta*, Article 3.

¹²⁴ *ibid*, Article 4. As will be discussed later on, the use of the term "universal" in the objective is, however, confusing since both the health care services and the drugs offered for the beneficiary are limited.

require contributions from members in social health insurance scheme, members' and employers contributions are common in most social health insurance scheme. Investment as a source of finance for the social health insurance is not, however, as common, and not clear, regardless of the Regulation's scant attempt to answer the 'why' question.¹²⁵

The health care benefits stipulated under the health service package¹²⁶ may be obtained from the health facilities which have concluded a contract with the Agency.¹²⁷ These health facilities are to 'provide services to the beneficiaries in accordance with the required quality standards, and with the tariff stated in the contractual agreement entered into with the Agency.¹²⁸ Any health facility which fails to comply with this [obligation] will be subject to criminal and civil liability, on the basis of relevant law.¹²⁹ Moreover, for periodic evaluation of the Agency, health facilities are obligated to furnish information on the provision of their services as per the required quality standards and their fulfilment of other quality requirements.¹³⁰

A health facility is expected to submit its aggregate health service bills to the Agency within 45 days after the end of the month in which the service is provided, failing which it will be liable to a fine of 1% of the amount of the late claim.¹³¹ Upon taking receipt of the bill, the Agency verifies and pays

¹²⁵ Article 4 (5) of the Regulation reads "The Agency may, to strengthen the financial sources of the Social Health Insurance Scheme, invest, pursuant to directive of the government, accumulated contribution remaining after deducting reserve funds". Yet, as the author was not able to acquire information from the Agency, at the time or writing it is unknown whether the directive which is to regulate the manner in which the Agency engages in investment activities has been issued or not. One would wonder the activities that the Agency chooses to invest on, as it will have a huge impact (positive if it succeeds and negative if it fails) on the health care package in general and on access to medicines in particular. This is because, as Article 4 (5) states, the objective of the investment is to strengthen the financial sources of the social health insurance scheme. Pursuant to Article 3 (3) of the Regulation, the fact that the Agency is in a strong financial status means it will be in a position to recommend to the government to expand the health service package laid down under the provisions of Article 3 of the Regulation.

¹²⁶ Social Health Insurance Scheme Regulation No. 271/2012, Article 3.

¹²⁷ Proclamation No. 690/2010, Article 3 (1).

¹²⁸ Regulation No. 271/2012, Article 6 (1).

¹²⁹ *ibid.* Article 6 (3).

¹³⁰ *ibid.* Article 6 (2).

¹³¹ *ibid.* Article 7 (1) & (3).

the amount to the health facility no later than three months from submission of the bill.¹³² The Agency is liable to pay interest (on the unpaid amount at the prevailing bank lending interest rate) if it fails to settle accurate health service bills, in accordance with Article 7 (2).¹³³ Apart from settling bills after the delivery health care service, the Regulation also envisages prepayment, the particulars of which are left to be dealt with a directive to be issued by the Agency.¹³⁴

The Ethiopian Health Insurance Agency is the body charged with implementing the health insurance system. It is established in accordance with Regulation No. 191/2010. Apart from the expansive powers and duties it is endowed with its constitutive instrument, the Agency also bears a range of powers and duties pursuant to the Proclamation and the Regulation.

2.2. Contributions of the Social Health Insurance Scheme to Access to Medicines

Many insurance systems were developed with the primary focus on reducing catastrophic health expenditures, especially those associated with hospitalization.¹³⁵ However, given high out-of-pocket spending on pharmaceuticals, an insurance scheme with no or limited medicines coverage may not prevent cost-induced poverty from medicine expenditures.¹³⁶ According to Faden, evidence from high-income countries suggests that higher medicines out-of-pocket co-payments result in lower utilization and poorer health outcomes; reducing or eliminating out-of-pocket medicines payments through insurance coverage in low- and middle-income countries should translate into greater access to medicines,

¹³² *ibid.* Article 7 (2).

¹³³ *ibid.* Article 7 (4).

¹³⁴ *ibid.* 7 (5).

¹³⁵ Laura Faden et al, 'The Role of Health Insurance in the Cost-Effective Use of Medicines', WHO/HAI Project on Medicine Prices and Availability, Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper 2 (2011) p.2. <
www.haiweb.org/medicineprices/05062011/Health%20insurance%20final%20May2011.pdf> 'accessed 27 October 2013'.

¹³⁶ Yip W, Hsiao WC, 'Non-evidence-based policy. How effective is China's New Cooperative Medical Scheme in reducing medical impoverishment'. *Social Science & Medicine*, 68: 201 (2009), in Faden et al (n 42 above) p.2.

improved health outcomes and increased satisfaction with the health care system.¹³⁷ In fact, studies undertaken by Dror et al. have shown that consumers place higher value on insurance schemes that include medicines coverage.¹³⁸

Nevertheless, not all health insurance schemes include medicines as one of the benefits of the system. Chalker notes that some insurance schemes will incorporate medicines as part of a comprehensive care package, others will compensate for them separately, and others will not cover them at all.¹³⁹ Yet, as expenses on medicines takes up the lion's share of the annual health care expenditure, it is only logical if health insurance schemes include the provision of medicines in their health services package. Apart from relieving its beneficiaries from out-of-pocket spending on medicines, health insurance schemes also ensure the availability of medicines, since the availability of medicines, at times, is as exasperating as their affordability.

Faden's study, furthermore, shows that there is evidence providing that health insurance can improve consumer access to and utilization of pharmaceuticals as well as health outcomes and that health insurance reduces financial barriers to access.¹⁴⁰ Insurance is associated with a decreased likelihood of paying for medicines, decreased consumer expenditures on medicines, decreased out-of-pocket spending on medicines as percent of total health expenditure, and decreased reported financial barriers to purchasing medicines.¹⁴¹

As part of their health services package, most social health insurance contains the provision of certain pharmaceuticals for their beneficiaries. The health services package of the Ethiopian social health insurance scheme is no exception in this regard. It says any beneficiary of the social health insurance scheme has the right to receive from health facilities generic drugs included in the drug list of the Agency and prescribed by medical practitioners.¹⁴²

¹³⁷ Faden (n 42 above) pp. 2-3.

¹³⁸ DM Dror et al. 'Health Insurance Benefit Packages Prioritized by Low-Income Clients in India: Three Criteria to Estimate Effectiveness of Choice' *Social Science and Medicines* 64 (4) (2007) in Faden (n 42 above) p. 3.

¹³⁹ Chalker (n 4 above) p.8.

¹⁴⁰ Faden et al (n 42 above) p.9.

¹⁴¹ *ibid.*

¹⁴² Regulation No. 271/2012, Article 3 (1) (e).

The fact that medicines are part of the benefit package of the social health insurance means that beneficiaries of the system are relieved from out-of-pocket expenditures on drugs. Moreover, as the membership of the system is extended to encompass families of employees and pensioners, it means, if implemented to the fullest, that a certain portion of the population is covered. Thus, out-of-pocket expense for medicines by the beneficiaries is done away with, at least in respect of the drugs found on the drug list of the Agency. This would certainly have a positive impact on the percentage of out-of-pocket expenditure on medicines in the country, however small the number may be. It will certainly do its beneficiaries a world of good in terms of enhancing access to medicines and ensure their right to health.

3. Shortcomings of the Social Health Insurance Scheme

3.1. Beneficiaries of the System: Membership - not Universal Coverage

Only employees¹⁴³ and pensioners¹⁴⁴ may become members of the social health insurance scheme in Ethiopia.¹⁴⁵ Accordingly, an employee or a pensioner registered for the social health insurance scheme and paying contributions thereto is entitled to receive the benefit package¹⁴⁶ under the

¹⁴³ An employee is defined as any employee having a three month and above period of service and includes public officials, management staff, judges, prosecutors, members of the police, members of House of Peoples' Representatives, salaried members of the House of the Federation and salaried labor union officials. Members of the Defense Forces, however, are excluded. See Proclamation No. 690/2010, Article 2 (2).

¹⁴⁴ A pensioner is defined as any person receiving monthly pension payments from the Social Security Agency and includes survivors of a pensioner. See Proclamation No. 690/2010, Article 2 (3).

¹⁴⁵ Proclamation No. 690/2010, Article 5.

¹⁴⁶ Pursuant to Article 8 (1) of the Proclamation, the health service package to be provided to beneficiaries includes essential health services and other critical curative services. As envisaged by the Proclamation, the Regulation gives a list of health services to be obtained from health facilities which have entered into a contract with the Agency. The health services the beneficiary is entitled to receive are outpatient care; inpatient care; delivery services; surgical services; diagnostic tests and generic drugs included in the drug list of the Agency, and prescribed by medical practitioners. On the contrary, the following health services are excluded from the health service package: any treatment outside Ethiopia; treatment of injuries resulting from natural disasters, social unrest, epidemics, and high risk sports; treatments related to drug abuse or addiction; periodic medical check-up unrelated to illness; occupational injuries, traffic accidents and other injuries covered by other laws; cosmetic surgeries; organ transplant; dialysis except acute renal failure; provision of eyeglass and contact

social health insurance scheme, along with his/her families.¹⁴⁷In accordance with the guidelines developed by the Agency, every employer¹⁴⁸ is required to register all its employees with the Agency for the social health insurance scheme.¹⁴⁹ Similarly, the Social Security Agency is required to register all pensioners (including the survivors of the pensioners) with the Agency. Furthermore, the Law obliges members to provide accurate information about their family composition and use the service properly.¹⁵⁰

In line with Article 6 of the Proclamation, which states that members' and employers' contributions are two of the sources of finance for the social health insurance, both the Proclamation and Regulation stipulate detailed rules with regard to such contributions. Accordingly, members (i.e. employees) and employers each contribute to the social health insurance in the amount of 3% of the member's gross salary.¹⁵¹ Employers are required to transfer the contributions of their employees which they withhold from their monthly salaries together with their own contributions within a month.¹⁵² With respect to pensioners, the amount of contribution to the social health insurance scheme to be made by them and the government is

lenses; in vitro fertilization; hip replacement; dentures, crowns, bridges, implants and root canal treatments except those required due to infections; provision of hearing aids; health services provided to any beneficiary free of charge. See Regulation No. 271/2012, Articles 3 (1) (a-e) and 3 (2) (a-n).

¹⁴⁷ Family in the Proclamation comprises the spouse (a person married to a member) and children (natural, adopted or stepchild of a member who has not attained the age of 18 years and includes any child who is under the guardianship of the member in accordance with the law) of a member and includes mentally or physically impaired children of the member who have attained the age of 18 years but cannot sustain themselves. See Proclamation No. 690/2010, Article 2 (10).

¹⁴⁸ A public office, a public enterprise or any person that employs at least ten employees.

¹⁴⁹ See Proclamation No. 690/2010, Articles 5(2) and (4).

¹⁵⁰ *ibid*, Article 7(2).

¹⁵¹ Regulation No. 271/2012, Article 4 (1). This meets the terms of Article 9 (2) of the Proclamation, which states that 'an employee and employer shall make equal percentage contributions based on the salary of the employee'.

¹⁵² Regulation No. 271/2012, Article 4 (3). Although Article 4 (3) of the Regulation specifies one month as the time limit for the transfer of the contributions of employees and employers, Article 9 (3) of the Proclamation employs a rather vague term, i.e. "timely". The Regulation sure will clear any confusion in respect of transferring contributions to the Agency.

1% each.¹⁵³ The Social Security Agency is required to transfer to the Agency the monthly contributions of pensioners together with the matching contributions of the government within one month.¹⁵⁴

This shows that, as membership in the social health insurance scheme is only reserved for employees and pensioners upon payment of contributions on a regular basis, the majority of the people in Ethiopia remain uncovered.¹⁵⁵ It is in the nature of social health insurance scheme to incorporate a certain portion of the population, and the Ethiopian system is not different. Indeed, this is one of the main elements which differentiate social health insurance from private or universal health insurance schemes. In the process, however, the lack of access to medicines of the majority of the people in Ethiopia continues unresolved, since a large majority of the population is engaged in the informal sector, not to forget the vast unemployment and, thus, are excluded from the membership of the scheme. Put otherwise, with over 90 million people, the majority of which lives below the poverty line and with various health concerns, the contribution of the social health insurance scheme is undermined. The fact that only 20,390 employees have been registered for the social health insurance scheme in the Ethiopian Fiscal Year of 2006¹⁵⁶ (2013/2014, i.e. about four years into the entry into force of the Social Health Insurance Proclamation) out of a staggering total population of over 90 million speaks volumes on how the scheme has left millions of people behind.

¹⁵³ Proclamation No. 690/2010, Article 9 (1) and Regulation No. 271/2012, Article 4 (2).

¹⁵⁴ Proclamation No. 690/2010, Article 9 (4) and Regulation No. 271/2012, Article 4 (2).

¹⁵⁵ The fact that a small portion of the population is covered by the social health insurance, however, is not peculiar to the social health insurance scheme in Ethiopia when one sees the situation in other similar countries. According to Berkhout and Oostingh, in low- and middle-income countries, where the majority of the population are employed in the informal sector (which in some countries absorbs 80 per cent of the economically active population) and where there are large rural populations, weak administrative capacity, and a lack of government stewardship, social health insurance is generally not considered a viable option. Esmé Berkhout and Harrie Oostingh, 'Health insurance in low-income countries: Where is the evidence that it works?' Joint NGO Briefing Paper (2008) p.13 <http://oxfam.qc.ca/sites/oxfam.qc.ca/files/2008-05-07_health_insurance.pdf> 'accessed 29 October 2013'.

¹⁵⁶ Federal Democratic Republic of Ethiopia, Ministry of Health, HSDP Annual Performance Report, EFY 2006 (2013/2014) Version 1 p.90.

This, however, should not be taken to undermine the contribution of the Scheme on access to medicines. The social health insurance and its benefit package, regardless of its shortcomings, is commendable on the part of the government in bringing the beneficiaries a step closer to health care services. However, as has been said above, with the small number of employees and pensioners as compared with the total number of population in Ethiopia, it is easy to conclude that the majority of the population still remains outside the scheme. The government is, therefore, challenged to build on this and expand the social health insurance with a view to using it as a transition to universal health coverage, however difficult the transition appears.¹⁵⁷ It is also expected to keep an eye on the Agency, which appears to be moving at a snail's pace, so that it can act faster and enable the beneficiaries of the system enjoy what they are entitled to.

3.2. Formulary: The Drug List of the Agency

It is acknowledged that the inclusion of drugs as a benefit in the Ethiopian social health insurance scheme is admirable, irrespective of the genre of the drugs. Indeed, beneficiaries of the system are relieved from out-of-pocket spending on the drugs that have made it into the drug list of the Agency. Yet, the fact that a restricted formulary is employed means that there are still a whole lot of medicines that the beneficiaries have to find and purchase on their own. The availability and affordability of drugs outside the Agency's formulary endangers the access to medicines of the beneficiaries and puts a question mark on the entire system in terms of ensuring access to medicines.

Indeed, limiting the available drugs amid their inclusion in the benefit package is common in most health insurance systems. Carapinha et al. state that most insurance programs come up with a list of the medicines covered under the system and others use a negative list, i.e. medicines excluded

¹⁵⁷ One can appreciate that achieving universal coverage through social health insurance is not an easy process. Carrin and James state that many countries that currently have a universal coverage system often needed decades to implement it: as at 2005, twenty-seven countries have established the principle of universal coverage via social health insurance. Guy Carrin and Chris James, 'Social Health Insurance: Key Factors affecting the Transition towards Universal Coverage', *International Social Security Review*, Vol. 58, 1 (2005), pp. 1 & 3. <www.who.int/health_financing/documents/shi_key_factors.pdf> 'accessed 28 October 2013'.

from reimbursement.¹⁵⁸ This is to say that Article 3 (1) (e) of the Regulation has not brought about something new by stating the benefit includes drugs only included in the drug list of the Agency.

Whether common or exclusive to the Ethiopian system, a drug list has its own disadvantages. One of the disadvantages of a drugs list, and as shown in Engelbrecht's study, is the fact that some drugs are included in the list for their price per tablet but not based on evidence of their essentiality.¹⁵⁹ Thus, it will be interesting to see the criteria¹⁶⁰ the Agency has taken in including the medicines in the drug list. Furthermore, the list is expected to be updated on a regular basis taking into account the medicines the Agency is in possession of.¹⁶¹ If this is the case, the Agency is again expected to make such an update known to the beneficiaries.

Therefore, in ensuring access to medicines to its beneficiaries, the criteria taken by the Agency in developing the drugs list are all the more important. With a view to avoiding the blunder of some other systems on their respective formularies, such criteria should be based on the essential

¹⁵⁸ See Carapinha JL, et al, 'Health insurance systems in five Sub-Saharan African countries: Medicine benefits and data for decision making' Health Policy(2010) <www.afro.who.int/en/downloads/doc_download/6154> 'accessed 27 October 2013'.

¹⁵⁹ See Susanna G Engelbrecht, 'Adherence to the Medicine Code List in Primary Health Care Military Clinics in Gauteng' (MA dissertation, University of Limpopo 2010).

¹⁶⁰ In studies undertaken by Carapinha et al. in five Sub-Saharan countries, it can be observed that different kinds of criteria have been employed in deciding the medicines the benefit covers. Such criteria are regulatory authority approval; being on the market for a certain time; being listed on insurance formulary; being listed on national essential medicines list; being shown to be cost-effective; being available at certain negotiated price. See Carapinha et al, (n 65 above) p.5. Needless to say, some of the criteria mentioned above do not solve the access gap and seem to have missed the whole point of including drugs in the benefit package. After all, a medicine should be included in a formulary not to increase the list of the medicines found therein, but obviously to enhance the health status of the beneficiaries of the system and help in the availability and affordability of medicines.

¹⁶¹ The frequency that it takes to update a formulary depends on the system and varies from one another. Again Carapinha et al. state that the experiences in the five Sub-Saharan countries show that some systems update their formularies more frequently than once a year; others update them yearly; every 2-5 years; less frequently than every 5 years. See Carapinha et al, (n 65 above) p.5.

medicines list¹⁶² and definitely not based on the medicines available to the Agency.

3.3. Category of Medicines: Generic

As part of the health care package of the social health insurance scheme, only generic drugs, included in the drug list of the Agency and prescribed by medical practitioners, are available.¹⁶³ The Regulation defines a generic drug as 'any drug marketed under its scientific and chemical name without trade name protection'.¹⁶⁴ On its part, the WHO defines generic drugs as:

a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights. Generic drugs are marketed under a non-proprietary or approved name rather than a proprietary or brand name.¹⁶⁵

Thus, as generic drugs involve no R&D of any sort for their development, the drugs are exceptionally cheaper than their brand counterparts. It may sometimes happen that brand medicines may be a thousand percent expensive than generic ones. As a result, brand medicines are way out of the reach of the poor. Hence, the fact that generic drugs are explicitly referred to under the Ethiopian social health insurance Regulation is understandable. The Agency, with the available fund, includes generic drugs into its formulary, as it seeks to address the access gap in the country by covering as many members as it can.

¹⁶² Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. World Health Organization, 'Equitable Access to Essential Medicines: A Framework for Collective Action', (2004) Geneva (WHO Policy Perspectives on Medicines) <www.who.int/hq/2004/WHO_EDM_2004.4.pdf>. Hence, an essential medicines list contains the list of medicines that are vital to the health care needs of the public and the Agency is expected to follow suit in developing the drugs list.

¹⁶³ Regulation No. 271/2012, Article 3 (1) (e).

¹⁶⁴ Regulation No. 271/2012, Article 2 (3).

¹⁶⁵ Generic Drugs, (World Health Organization, 2014) <<http://who.int/trade/glossary/story034/en/>> 'accessed 26 September 2014'.

As has been discussed elsewhere, generic drugs are not to be produced from those drugs produced since 1994, except for the transition periods granted to developing country members of the WTO. As all the major generic producing countries are members of the WTO, the availability of generic medicines is diminishing by the day, since they cannot produce generic drugs out of the brand ones whose respective patents are pending.

Apart from difficulties associated with intellectual property rights, generic drugs also have another problem relating to its effectiveness. McIntyre claims that it is difficult to be sure about the quality and strength of some generic drugs.¹⁶⁶ This is irrespective of the fact that all the active ingredients of a generic drug are the same as that of the brand. This, therefore, does not help in realizing the right to health of at least the members of the scheme.

4. Towards a better Formulary: The Role of Donors, Pharmaceutical Companies and NGOs

The public has the right to health, and the primary responsibility of ensuring the right falls on the state. This responsibility is assumed by states based on their respective national laws as well as international laws, both customary and conventional. The state needs to explore every possible option for that to happen. The argument throughout is that medicines have a big role to play in the realization of the right to health, and that it is the government that is supposed to ensure their availability. This section tries to assess the roles of donors, pharmaceutical companies and NGOs in helping the Agency in its bid to possess medicines, both in quality and quantity, by working in close contacts with development partners.¹⁶⁷

4.1. Aid

The role of aid in enhancing access to medicines may not sound plausible, as the major causes of the problem are also the major partners.

¹⁶⁶ Peter McIntyre, 'Drug donations: treat or treatment?' (Cancer World December 2006-January 2007 Special Issue) p.24 <http://axios-group.com/index.php/download_file/view/102/107/> 'accessed 4 November 2013'.

¹⁶⁷ According to the HSDP IV Annual Performance Report, pharmaceuticals, medical supplies and equipment worth of Birr 3.77 billion were donated by development partners and received at the Pharmaceutical Fund and Supply Agency warehouses in the Ethiopian Fiscal Year of 2006 alone. This clearly shows how big a role development partners play in this regard.

Industrialized countries, where most of the aid comes from, continue to put pressure on developing and least developed countries' endeavor to ensuring access to medicines to their public.¹⁶⁸ That said, it is maintained that the role of aid should not be dismissed under the circumstances. Apart from aid from governments, aid may also be sought from international organizations such as the WHO, the World Bank and others working on the area.

The modality of aid in this context may take the form of financial aid to the Agency's fund or the supply of medicines directly into the Agency. Indeed, the supply of medicines instead of financial aid seems a better alternative, for all the right reasons. That way, the Agency would be in a position to have a better supply of medicines, as well as expand its formulary, at least on a momentary basis. Hence, much is expected from the Agency in terms of soliciting both the financial aid and the pharmaceuticals from the donors.

If the Agency succeeds in securing an ever increasing aid, it will certainly play a significant role in reducing the access gap in Ethiopia. As has been discussed above, only generic medicines are available as part of the health service package of the social health insurance scheme in Ethiopia, the availability of which continue to be threatened by the day. If the Agency succeeds in soliciting aid and harbours a well-off depot of drugs, it would be a great contribution to access to medicines, at least for the portion of the population the system is designed to cover.

4.2. Access Initiatives of Pharmaceutical Companies: Donations and Price Reductions

Money being lost by pharmaceutical companies was the driving force for the negotiation of intellectual property agreement at the Uruguay Round. Industrialized countries, which are home to these research-based pharmaceutical companies, continue to put pressure on countries even long after the entry into force of the WTO Agreement. As much as they are the sources of the access problem, however, and whatever their motives may

¹⁶⁸ A very good example of this is the United States Section 301 of the Trade Act, which the US applies to impose trade sanctions under any trade agreement (whether bilateral or multilateral) where US interests are "being denied" by the act, policy or practice of another country.

be,¹⁶⁹ pharmaceutical companies do contribute in promoting access to medicines in developing and least developed countries. Such contributions made by pharmaceutical companies may take the form of donations of a given drug[s] or it may involve a price reduction of a given drug to the needy that cannot otherwise afford the drugs.

With regard to donations, one may come up with a number of instances whereby pharmaceutical companies lend their support to enhance access to medicines to the needy. Among these donations, Boehringer-Ingelheim's offer to provide Nevirapene, a drug proven to reduce the mother-child transmission of HIV drastically, free for a limited period of time¹⁷⁰ is one notable example. Moreover, under the WHO sponsored Alliance to Eliminate Filariasis, GlaxoSmithKline agreed to donate all needed supplies of its drug, albendazole, and Merck similarly agreed to donate ivermectin free of charge until the disease is eliminated.¹⁷¹ Pfizer, on its part, has agreed to provide free fluconazole to South Africans affected by cryptococcal meningitis.¹⁷²

Apart from the donations they make, pharmaceutical companies also introduce price reductions on their products for some of the poorest people of the world. Bristol-Myers Squibb, for instance, announced to reduce the prices of two widely used AIDS drugs, ddI and d4T, to about USD 500 in Senegal.¹⁷³ Merck provided a USD 50 million donation, primarily in the form of a price reduction (matched by another USD 50 million by the Gates Foundation) to Botswana.¹⁷⁴ Johnson & Johnson made its first HIV/AIDS medication available to patients in sub-Saharan Africa and other less

¹⁶⁹ See University of Pretoria, Access to Medicines Course Book (Reader), (unpublished) Advanced Human Rights Course on Intellectual Property, Trade, Human Rights and Access to Medicines in Africa, Centre for Human Rights, May 2012, p.188. Pharmaceutical companies share a duty to ensure adequate health standards in poor countries... However such moves by pharmaceutical companies are geared at improving their image amid accusations of their materialistic goals.

¹⁷⁰ UdoSchüklenk and Richard E Ashcroft, 'Affordable access to essential medication in developing countries: conflicts between ethical and economic imperatives' *Journal of Medicine and Philosophy*; 27(2): (2001) p.179. <www.udo-schuklenk.org/files/access.htm> '4 November 2013'.

¹⁷¹ Access to Medicines Course Book (n 76 above) p.188.

¹⁷² Schüklenk and Ashcroft, (n 77 above).

¹⁷³ *ibid.*

¹⁷⁴ *ibid.*

developed nations at a price that is 85 percent lower than the U.S. commercial price.¹⁷⁵

As with aid, the Agency needs to pull the strings in creating strong ties with pharmaceutical companies with a view to expanding its drugs list. This is of course in line with target 8 (17) of the MDGs, which states that ‘in co-operation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries’, which is measured by ‘proportion of population with access to affordable essential drugs on a sustainable basis’.¹⁷⁶ Although, aid as well as donations and price reductions are unilateral in nature and thus may be withdrawn at anytime, it is maintained that the Agency may do a remarkable job in bringing the beneficiaries of the system a step closer to important medicines.

4.3. NGOs working on Access to Medicines/the Right to Health

NGOs have done a remarkable job in alleviating various problems of societies virtually in all corners of the world. Similarly, many NGOs have been engaged in promoting access to medicines through different ways. VSO, Oxfam, Christian Aid, The Essential Drugs Project, Action Aid, Save the Children Fund and many others have been working on access to medicines and related issues for several years.¹⁷⁷

There are countless NGOs in almost all parts of the world that have positively impacted the promotion and protection of human rights. The same applies when it comes to access to medicines. NGOs have been integral to promoting a rights-based approach to pharmaceutical policy and pressing for more comprehensive corporate awareness of, and responsibility for, access to medicines.¹⁷⁸ In recognition of NGOs’ value, the

¹⁷⁵ Johnson & Johnson, Access to Medicines<www.jnj.com/responsibility/ESG/Social/Global_Health/Access_to_Medicines> (11 January 2013)

¹⁷⁶ Millennium Development Goal 8 (17) + (46).

¹⁷⁷ ‘Increasing access to essential medicines in the developing world: UK Government policy and plans’ Department for International Development (2004) p.18.

¹⁷⁸ Leisinger et al (n 22 above), p.4.

Millennium Declaration recommends that greater opportunities be given to NGOs to contribute towards global health goals.¹⁷⁹

A number of international NGOs have been working towards ensuring access to medicines to the poor. Examples include Health Action International (HAI) The Access to Medicine Foundation (ATM), VSO, Oxfam International, Christian Aid, The Essential Drugs Project, Médecins sans Frontières (MSF), Action Aid, Save Alliance, Rockefeller Foundation, Bill and Melinda Gates Foundation, Carter Center, Lions Clubs International, USAID, Plan, Action for Global Health. These organizations, either on their own or in collaboration with national NGOs, may contribute in bringing medicines within the reach of the poor. In the Ethiopian context, with all the problems the Charities and Societies Law¹⁸⁰ poses with regard to the involvement of NGOs in ensuring access to medicines in Ethiopia, it is acknowledged that they have a lot to offer.

¹⁷⁹ UN General Assembly Resolution 55/2. United Nations Millennium Declaration in Leisinger (n 22 above) p.4.

¹⁸⁰ Although the advancement of human rights is included as charitable purposes under the Proclamation, only Ethiopian charities/societies may engage in such activities. Access to medicines, as a basic component of the right to health, may fall in the category which is open to only a limited number of NGOs. However, access to medicines is not only a major component of the right to health, but also plays an important role in the poverty reduction endeavours. As is known, ill-health is one of the factors enhancing poverty. According to Xu et al., worldwide every year 150 million people face catastrophic health-care costs because of direct payments, while 100 million are pushed into poverty – the equivalent of three people every second. See Xu et al, 'Protecting households from catastrophic health spending' (2007) *Health Affairs*, 26(4): 972, in Averill, (n 8 above) p.11. Furthermore, a study undertaken by Pfizer shows that between 50 to 90 per cent of annual total health care expenditures by the world's poorest people, approximately \$30 billion annually, go to pay for medicines. See Pfizer (n 21 above) p.29. The WHO estimates that diseases associated with poverty account for 45 per cent of the disease burden in the poorest countries. WHO, World Health Report, (2002) <www.who.int/whr/2002/>. Although the total expenditure of poor countries like Ethiopia on medicines is too low as compared with industrialized countries, expenditures on medicines remain one of the highest. Arguably, NGOs working on poverty reduction and alleviation should be allowed to contribute, in collaboration with the Agency, in reducing the access gap in Ethiopia, not only as a major component of the right to health/life, but also in terms of alleviating poverty in the country. This is of course, as noted above, in line with the Millennium Declaration's recommendation that greater opportunities be given to NGOs to contribute towards global health goals.

The forgoing discussion goes to show that NGOs, along with their efforts in campaigning¹⁸¹ against western influence, may also contribute in expanding the drug list and availability of the formulary of the Agency. Thus, it is interesting to see the extent to which the Agency makes use of NGOs in its endeavour to endow the members of the insurance scheme with vital medicines essential for their health. Needless to say, this helps not only in ensuring the right to health of people, but also reduces the out-of-pocket expenses (for those who are able to pay) which in turn positively impacts the fight against poverty.

Concluding Remarks

Medicines play an enormous role in ensuring the right to health. In the poor parts of the world, especially in many parts of Africa and Asia, the challenges on access to essential medicines are, however, as enormous. One may point his fingers on a number of factors on access to medicines. Poverty, national laws and policies and international agreements are some of the factors that keep medicines out of the reach of the majority in many parts of the world.

The access gap gets worse in countries like Ethiopia as people pay for their medicines. It really is ironical to witness the fact that people in such countries cannot even afford to pay for generic drugs, the price of which is, in most cases, extremely low than the corresponding brand medicines. Ways to mitigate the out-of-pocket expenditures on health care services in general and medicines in particular should be sought and implemented.

One such means is employing health insurance schemes, which incorporates medicines as one of the benefits in the package. Ethiopia had recently introduced a social health insurance scheme through the Social Health Insurance Scheme Proclamation No. 690/2010 as implemented by

¹⁸¹ A number of NGOs have been campaigning against pharmaceutical companies and their respective governments for increasing the access gap. The campaign by Médecins Sans Frontières is one such example. According to Ford, its campaign is firmly rooted in, and guided by, the experience of its medical professionals working throughout the developing world, it is the injustice seen at local level among some of the most marginalized groups in the world, who die because they cannot access basic medicines, that drives advocacy at international level. See Nathan Ford, 'Patents, access to medicines and the role of non-governmental organizations', *Journal of Generic Medicines* Vol. 1 No 2. (2004) p.139.

the Social Health Insurance Scheme Regulation No. 271/2012 and the Ethiopian Health Insurance Agency which is established by Regulation No. 191/2010. Although the Council of Ministers immediately issued the Regulation which established the Agency, it took more than twenty seven months for the Council of Ministers to issue the implementing Regulation.

The fact that the social health insurance scheme includes medicines as part of its health service package inspires optimism in terms of enhancing access to medicines to the beneficiaries of the system. That said, the social health insurance scheme is not a finished article in ensuring access to medicines in the sense that it also suffers from certain shortcomings. In order for one to benefit from the social health insurance scheme, s/he has to be a member, which is not of course exclusive to the Ethiopian system, which is only reserved for employees and pensioners (and their families). In a country like Ethiopia where an overwhelming majority of the population is engaged in in the informal sector together with the vast unemployment, it is safe to conclude that the system has left tens of millions of people behind. These people are, therefore, required to make out-of-pocket spending on important lifesaving medicines, which, because of its enormous amount, is a setback to the fight against poverty. Issues associated with a drug list as well as generic medicines are also problems to reckon with.

Moreover, to make matters worse, the Agency is moving too slowly in implementing the laws, and is, therefore, aggravating the problem. Five years into the entry into force of the Proclamation and the Agency seems to be boasting about the 20,000 plus people it has registered, the number of new employees it has recruited, the trainings and meetings it holds week in week out and so on. It is only logical to rely on organs of the government having oversight on the Agency (such as the Ministry of Health and the House of Peoples' Representatives, among others) to make proper assessments of the Agency's activities so far and maintain a close follow-up.

The Agency is expected to actively engage in activities that would enhance the access to medicines of the members the social health insurance scheme covers. It should work hard in terms of utilizing the available options in the generous arrangements of aid agencies/governments, NGOs, research-based pharmaceutical companies as well as other organs. It should expand its formulary, both in quality and quantity, using the options discussed in above and others.