The World in 2050: How can the European Commission ensure Access to Medicines?
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A Scenario Planning

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1. Introduction

2346 in Guinea, 3857 in Sierra Leone and 4408 in Liberia. These are the confirmed deaths due to Ebola on the 12th of April 2015 (CDC, 2015). Many claim that the international community failed horribly to adequately respond to the strongest and most devastating Ebola outbreak ever. From August 2014 until December 2014 the incidence rates and death rates exploded. Only since January 2015 and the arrival of adequate medication and vaccination the curve flattens and the countries are close to being declared Ebola-free by the World Health Organization (WHO). However, the question remains: Why did the international community act so slowly and what would have been alternatives?

Certainly, the lack of medication at the time of need might provide one part of the answer to why this outbreak became so huge. One might even ask how many deaths could have been prevented, if access to medication had been timely. Such an outbreak is, of course, a worst case scenario, but the problems of lacking access to medicines are present problems and have only been further emphasized by the Ebola-outbreak. An estimated 2 billion people had no access to medicines as calculated by the Access to Medicines Index in 2014 (Access to Medicine Foundation, 2014).

Although prevention programs and health literacy efforts are effective policies in preventing disease (Mackenbach, Karanikolos & McKee, 2013), the main area to solve medical problems remains the pharmaceutical sector. This is also represented by the amount of GDP that is spent. While only 3 % of GDP is spent on prevention, pharmaceutical companies invest billions into research & development of medication (Paul et al., 2010). Thus, medicines are of uttermost importance and access to them is crucial.

The consequences of having no or inadequate access are clear and straightforward. Unaffordable prices lead to impoverishment (Krishna, 2006). In the worst cases a lack of timely access may even result in death (Newton, Green, & Fernández, 2010).

Access is defined by Peters et al. (2008) as the timely use of a service according to need. With regard to medicines several other dimensions, such as appropriate use or affordability, may be identified. For instance, a WHO study found that 50% of medicines are not appropriately prescribed, whereas equally many people do not know how to adequately use them (World Health Organization, 2004). Affordability refers to the adequate price level and may constitute a barrier for many services, especially medication (Jacobs, Ir, Bigdeli, Annear, & Van Damme, 2012).

The European Commission (EC) and the international community acknowledged the problem and agreed to dedicate one Millennium Development Goal (MDG) to increase access to medicines. Via different strategies the community might be able to achieve this goal. In line with the Council

Conclusion on Global Health (European Council, 2010) the European Commission has to become one of the main players in global health which further stresses the need to find solutions to the access problems, even further fuelled by the Ebola crisis. Using scenario planning this paper tries to anticipate future scenarios based on the current driving issues such as antimicrobial resistance and changing disease patterns. Various possible strategies that may be useful for the European Commission will be applied. Such an exercise is useful to initiate an open debate on the various possibilities that may help to achieve a desired future or at least prevent worst case scenarios.

2. Methods

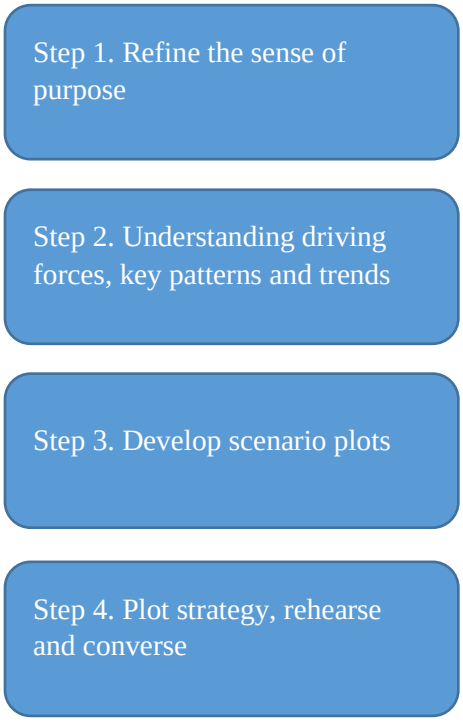
The financial sector and especially businesses make use of scenario planning to anticipate the future and design strategies to prepare for a variety of possible pathways (Venable, Ma, Ginter, & Duncan, 1993). For public health this method becomes increasingly important as well because the complex interactions between the environment, economy, political set-up and individuals & populations health are paved with many uncertainties, risks and a tremendous lack of reliable data and models (Neiner, Howze, & Greaney, 2004). Martakis (2013) for instance, applied scenario planning to explore the possible future effects of climate change on population health and designed various strategies for the European Commission to tackle each of the driving factors.

To the best of my knowledge scenario planning to anticipate the effects of lacking access to medicines has not yet been applied in the scientific literature. This paper tries to close this knowledge gap and provides a first attempt to design appropriate strategies that may be improved in the future as knowledge about the driving forces advances. With regard to determining the future access to medicines this method is a useful tool to account for the driving factors and key patterns that exist in order to anticipate future scenarios and identify strategies for the European Commission to increase the access to medicines within European Member States but also globally.

Scenario planning in public health follows four major steps which are pictured in Figure 1. The purpose and relevance of the issue should be clearly defined (step 1: refine the sense of purpose). In order to build scenarios the driving forces and key patterns need to be identified (step 2: understand driving forces or key patterns and trends). Driving forces can be both predetermined and unpredictable. For instance, an ageing population is a relatively predetermined driving force whereas the occurrence and spread of innovation or the public interest is hardly predictable. As a third step the scenario plots need to be developed. At this stage it is important to understand the driving forces and their impact on access to medicines. The likeliness of scenarios is subordinated compared to the understanding of the difficult interactions and how the driving forces may influence the access to medicines (step 3: develop scenario plots). The final step 4 (plot strategy, rehearse and converse) constitutes the core added value of scenario planning. The researcher should develop strategies that may help to tackle the future problems.

Discussions about the plots as well as public debates may help to continuously develop the scenarios and refine certain strategies (Neiner et al., 2004).

Figure 1. Scenario Planning Steps



Source: Neiner et al. (2004)

3. Results

In the following section the results of each step are presented followed by a detailed description of each scenario plot and the development of certain strategies.

Step 1: The sense of purpose

The access to medicine index (ATMI) (Access to Medicine Foundation, 2014) funded by the Bill & Melinda Gates Foundation as well as the Dutch and British governments estimates that in 2014 approximately 2 billion people had no access to medicines. Health is a globally recognized human right (United Nations, 1948) and medicines are still the major source of cure for many diseases. Therefore, the World Health Organization (WHO) acknowledged the need to improve access to available and affordable medicines and incorporated a specific target into the Millennium Development Goals (MDG 8e) (United Nations, 2008).

The European Union, meanwhile, adopted a council conclusion on the EU´s role in Global Health (European Council, 2010) in which it specifically stresses the EU´s central role in achieving the MDGs

and further specifies its engagement to support that the main components of health systems including access to medicines will be strengthened globally.

At this stage it is not only important to specify the sense of purpose but also the complexity related to the concept of access to medicines. Whereas medicines are straight forward, access is a complex concept consisting of many dimensions.

Access to medicines has been defined by the United Nations Development Group (UNDP) as "*having drugs continuously available and affordable at public and private health facilities or drug outlets that are within one hours walk of the population"* (United Nations, 2008). Several dimensions may be identified related to the concept. While the UNDP definitions recognizes the dimensions of availability, geographic accessibility and affordability, the European Commission identifies additional dimensions such as efficacy, cultural acceptability, safety, quality and the appropriate use of medicines. The general assumption related to these dimensions is that any improvements may lead, theoretically, to an increase in access to medicines.

Step 2: Driving forces, key patterns and trends

The main challenge for the anticipation of future scenarios is to understand the driving forces and key patterns which are to a small degree predetermined but mostly unpredictable. The driving forces that affect the access to medicine can be summarized under the umbrella of demand and supply mechanisms since medications, at the end of the day, are manufactured products subject to economic market rules (Jacobs et al., 2012). However, both the demand side as well as the supply side are interrelated with other driving factors such as an ageing population, innovations and politics. Furthermore, economic rules may be altered by statutory institutions which can establish new playing grounds and equally address both demand and supply side.

The key actors are on the one hand, pharmaceutical companies and doctors (supply side) and on the other hand, patients (demand side). Both camps may be addressed by legislative institutions such as the European Commission and national governments but also non-governmental organizations such as the World Health Organization.

Considering the umbrella of the demand side the following predictable and unpredictable forces are related to the demand of medications that ultimately determines their access. The ageing population with the key trend of increasing multi-morbidity among elderly and changing lifestyles towards more chronic diseases changes the demand for new drugs (Marengoni, Winblad, Karp, & Fratiglioni, 2008). The new disease patterns require new forms of medications and treatment. This trend is fuelled by increasing

mobility and the changes in living patterns. Increasingly abandoned rural areas constitute a threat to the geographic accessibility of medicines for the people that remain in these areas.

Other factors that shape the demand for medications – other than the plain need - is the health literacy of patients which is closely related to their socio-economic-status (Schillinger et al., 2002). Knowing the side effects or about prevention strategies may reduce the demand for unnecessary medications.

On the supply side a key trend to take into consideration is the increasing resistance of antimicrobials – one of the most powerful ingredients for today's most effective medications (Bronzwaer et al., 2002). If such an ingredient loses its power, the pharmaceutical companies need to be innovative in order to maintain their status and continue to serve the health of the population. These innovations, however, are unpredictable and may relate to many sectors such as personalized medicine. Certainly, high development costs in an increasingly unstable economic market bare the risk of resulting in unaffordable prices for new medications and pills, thus contributing to a decrease in access to medicines and an increase in global health inequalities (Taylor & Al-Saeed, 2010).

The ATM Index shows that pharmaceutical companies increasingly engage in new, integrated business models to facilitate access to medicines as well as in mechanisms that facilitate the market entry for generics ensuring affordability. However, the number of law suits against pharma giants for bribery of doctors and illegal patent extensions is still high and thus transparency issues remain high on the agenda (Access to Medicine Foundation, 2014).

All these factor may influence the access to medicines on a global level. Therefore, the scenarios will be based on the following key driving forces and patterns under the umbrellas of demand and supply:

- Demographic change, ageing population
- Mobility
- Antimicrobial Resistance
- Personalized Medicines
- Generics
- Politics and society

Step 3: Scenario Plots

It is important to note that the various dimensions of access can be affected either way by the demand and the supply side. Both may determine the ultimate percentage of the population that has access to medicines. The goal of this study is to identify strategies for the European Commission to facilitate the global access to medicines. Therefore, the level of EU influence, although it is unpredictable, is central to the development of scenarios. The scenarios should be

read with the following notes in mind. Scenario 1 and 3 refer to a high level of influence of the EC, while scenarios 2 and 4 relate to weak or no influence of the EC. Similarly, scenarios 1 and 2 deal with low success rates or worsened outcomes, while scenarios 3 and 4 show successful increases in access to medicine. The plots are presented in Table 1.

Step 4: Development of Strategies

The final step of scenario planning requires the development of strategies that steer the future towards the most desirable plot (Neiner et al., 2004). These strategies are illustrated in Figure 2. With regard to access to medicines scenario 3 might anticipate the future in a way that is desirable from the point of view of increasing access for a global population. The strategies shall not only help steering towards this future but also assist in avoidance of the remaining three scenarios.

Table 1. Scenario Plots

Driving Force	Background	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Ageing	The life expectancies across the globe are increasing but result in a higher burden of multi morbidity at old age. People suffer from more multiple chronic conditions. New disease patterns emerge raising different demands.	European Commission strengthens research efforts with financial assistance. However, mechanisms to effectively use the newly gained knowledge are lacking. People in developing countries remain at the lower end and inequalities are increasing globally because only the upper class can afford the new drugs. Furthermore, legal incentives to facilitate access to expensive medicines are missing.	The pharmaceutical companies are faced with new and complex disease patterns of multiple chronic conditions where most of the usual drugs remain ineffective. Only the few big pharma giants are able to deliver new drugs which are too expensive for most parts of the world. The European Commission has no answer to the problem and watches the barriers to access grow.	The prevention and health literacy efforts pay off. People age actively and healthy and thus the occurrence of new disease patterns remains relatively low. In addition, European investments in research facilities in developing countries allow researchers to investigate specific needs of the certain populations with regard to their ageing patterns.	Developing countries experienced far less strong changes in lifestyle habits and thus age healthier than the developed countries. The pharma sector has adapted to the new demands of the developed world in order to maintain its competitiveness The European Commission has almost no weight on the Global Health agenda.
Mobility	Stronger urbanization leaves people in rural areas at risk of being deprived of medicines, because rural areas lose their attractiveness for pharmaceutical companies.	Although the European Commission encourages the development of capacity building strategies its coordinating role does not meet the required solutions to improve the situation. People in rural areas experience a high burden to obtain the medications needed due to increasing travel costs.	Urbanization constitutes a major challenge for the infrastructure of cities and the resulting slums facilitate the spread of contagious diseases. Pharmaceutical companies lack the government's financial support which results in major supply shortages.	Capacity building efforts that relate to city infrastructure advancement as well as high speed transportation systems facilitate the access to medicines. The average time to reach the nearest drug outlet will be reduced to 12 minutes walking distance.	People re-discover the prospects of nature and urbanization loses its pace due to a wider distribution of the population. This development requires the pharma sector to find tailored solutions and to ensure an adequate level of supplies.
Antimicrobial resistance	The effectiveness of antimicrobials is rapidly decreasing mainly due to misuse and overuse among animals and humans. With the loss of antibiotics simple infections may advance to life threatening conditions similar to the middle age.	National governments set up new legal frameworks and guidelines for the use of antibiotics coordinated by the European Commission. However, these frameworks leave enough leeway and do not bring major change to the issue. The effectiveness still decreases and the lack of new solutions leaves many millions of people with drugs that are low in efficacy.	The citizens' health literacy decreases and resistance to antimicrobials increases. Hospitals and farms are full of resistant bacteria. Governments have failed to respond adequately and long absence at work leads to reductions in GDPs which results in a new financial crisis. Mortality rates are increasing rapidly.	Not only funding of research but also financial assistance in implementing new procedures facilitates the development of new drugs as substitute for antibiotics. Health literacy campaigns are effective in both protecting human and animal health.	Antibiotics continue to lose their effectiveness but as many times before in medicine a lucky coincidence has brought a substitute that may become the new general medication.
Innovations (Personalized medicines)	Personalized medicines promise important medium to long term benefits. However, the time and resources	Especially cancer rates and dementia are increasing and put the personal caregivers and healthcare systems under pressure. Existing	Almost no pharmaceutical company is able to invest in research to further develop personalized medicines. Partly because of the lack of	Public Private partnerships have become the standard model to invest in medical research. The branch of personalized medicines	An abuse of medical information in 2030 by many insurance companies fuels the public pressure on politics to finally address the

	needed for the development may constitute a great burden for public and private investors accompanied by many ethical and legal issues that require adequate attention.	technological treatments such as proton therapy have been advanced and only are really available in the developed world. Some European measures to assist informal caregivers exist but do not adequately reimburse the time effort. This leads to major constrains on GDP since the magnitude of absence at work rises exponentially with dementia rates.	legal attention and the missing effort to engage in public private research partnerships. Obesity rates have worsened since no attention was given to the genetic components that can determine the occurrence of obesity.	profits tremendously. However, transferring these expensive techniques to developing countries remains difficult, although capacity building especially regarding knowledge and research skills are picking up rapidly. In Europe and America people can, on request, receive information on their future health status. This information is protected and unavailable for insurance companies.	question of gene property. Similarly, intellectual property rights have not become more flexible and thus the few techniques that exist for personalized medicines are extremely expensive.
Generics	Generics are products that use the same medical ingredient but different manufacturing e.g. form, colour etc. The advantage is that a higher share of generics can lower the price of drugs because more choice/competitor drugs exist. However, the medical ingredient is subject to patents and IP rights which are protected for a long period of time. Companies tend to illegally prolong these protections in order to avoid competition on the markets.	A new patent monitoring scheme introduced by the European Commission does not work properly because companies find their niches to prolong their patents, thus increasing barriers for market entry of generics. The few blockbuster drugs that still exist become more expensive and remain unaffordable for most parts of the world.	Almost no generic manufacturers exist anymore. Illegal drug manufacturing has become a huge problem since pharmaceutical companies merged to 4 giant companies in 2040. These companies set a global reference price making it impossible for some of the least developed parts of the world to purchase essential medications. Inequalities have risen substantially.	Flexible regulatory frameworks allow to determine earlier market access for generics. A new integrated clinical trial procedure makes it possible that people can benefit from better access to medicines at an earlier stage. Incidence rates of contagious disease drive towards 0 in most parts of the world because joint procurements for vaccinations are working effectively.	More generic manufacturers emerge and succeed to build a natural competition on the pharmaceutical market due to various add on services at the time of purchase such as nutrition workshops and cooking lessons. The public spending on pharmaceuticals rises causing to cut costs at other important factors such as health promotion campaigns.
Politics / Society	The problem of access to medicines has been recognized by the EC and incorporated into the MDG of the WHO. DG SANTE´s efforts are of coordinating nature and there is lack of effective collaboration between national governments, the WHO and the EC to improve the access to medicines worldwide.	Although the EC worked hard to reduce overall prices of medicines Europe is still the most important market for the newly developed expensive drugs. Failure of bringing all stakeholders together suggests that the inadequate access to medicines is even worsening beyond the borders of the European Union.	The EC has failed to effectively address the problem in collaboration with other stakeholders. The MDG has not been met and now even more people experience a lack of access mainly due to the high prices and the geographical access.	The fruitful discussions between pharmaceutical companies, the EC, WHO and UN have brought various ideas that increased access to medicines. Amongst others, joint procurement agreements have been reached among stronger economies as well as new clinical trial regulations that allow faster access to medicines. The society actively engages in research projects in order generate high sample numbers and facilitate research efforts.	The fragmentation in the European Union regarding health policies still exists and makes it impossible for the EC to have a strong role in global health. Nonetheless, some economically strong governments, supported by the WHO, manage to export cheap high quality medication so that at least the essential medication is available.

Figure 2. Possible strategies for the European Commission (Source: own)

Capacity Building Assess and improve the capacities of developing countries with special regard to research skills and knowledge
Legislative Frameworks Develop strategies to address legal questions such as data protection, intellectual property rights, patent as well as clinical trials
Financial tools Develop frameworks to design flexible financial tools that allow effective pricing and help weaker economies to have essential medication
Prevention Develop, implement and monitor effective prevention strategies that reduce the demand for medication with a special focus on health literacy
Cooperation Make sure all relevant stakeholders come together early enough so that possible problem can be anticipated from the beginning and solved accordingly

4. Discussion

The aim of increasing access to medicines is dependent on mainly two driving forces - that is demand and supply. Both sides are interrelated and subject to major uncertainties. While the occurrence and developments of diseases and its patterns are mainly unpredictable, the demand side seems to be even more uncertain and unpredictable than the supply side. Although, the supply side still needs to adequately respond to the demands of patients, its activities may be more controllable than naturally occurring diseases. This is achieved mainly by regulatory and legislative strategies as has been outlined in the scenario plots.

However, other activities related to research will be of great importance as well. In times where the effectiveness of universal drugs such as antibiotics decreases, it is important to foster the research for substitutes or even develop more personalized solutions that incorporate the genetic structure of each patient. Such costly efforts may be supported by public financing since its development may have an impact on public health and certainly on the affordability of such solutions.

This paper has laid out various anticipated futures to the problem of increasing access to medicines. These scenarios and the proposed strategies may provide a starting point for public debate on a European level. Although, nowadays the mandate of the European Commission with regard to health is at best vague, international commitments to tackle the lack of access exist. The European Commission will have to work more closely together with international organizations and other Directorate Generals within the EU as well as industry stakeholders and researchers in order to foster a more coherent policy debate on the issues and problems related to access.

Time is precious when it comes to providing adequate medications at the right spot and time. Therefore, thinking about how to improve access in the future requires us to start acting today.

5. References

- Access to Medicine Foundation. (2014). Access to Medicine Index Harlem, Netherlands: Access to Medicine Foundation.
- Bronzwaer, S., Cars, O., Buchholz, U., Mölstad, S., Goettsch, W., Veldhuijzen, I., . . . Degener, J. (2002). A European study on the relationship of antimicrobial use and antimicrobial resistance. *Emerging infectious diseases, 8*(3), 278-282.
- CDC. (2015). 2014 Ebola Outbreak in West Africa - Case Counts. Retrieved 15.4.2015
- European Council. (2010). Council conclusions on the EU role in Global Health. *Brussels: Council of the European Union*.
- Jacobs, B., Ir, P., Bigdeli, M., Annear, P. L., & Van Damme, W. (2012). Addressing access barriers to health services: an analytical framework for selecting appropriate interventions in low-income Asian countries. *Health policy and planning, 27*(4), 288-300.
- Krishna, A. (2006). Pathways out of and into poverty in 36 villages of Andhra Pradesh, India. *World Development, 34*(2), 271-288.
- Mackenbach, J. P., Karanikolos, M., & McKee, M. (2013). The unequal health of Europeans: successes and failures of policies. *The Lancet, 381*(9872), 1125-1134.
- Marengoni, A., Winblad, B., Karp, A., & Fratiglioni, L. (2008). Prevalence of chronic diseases and multimorbidity among the elderly population in Sweden. *American Journal of Public Health, 98*(7), 1198.
- Martakis, K. (2013). The influence of the European Commission on health effects of climate change–The world in 2050: Scenario planning. *Albanian Medical Journal*.
- Neiner, J. A., Howze, E. H., & Greaney, M. L. (2004). Using scenario planning in public health: anticipating alternative futures. *Health promotion practice, 5*(1), 69-79.
- Newton, P. N., Green, M. D., & Fernández, F. M. (2010). Impact of poor-quality medicines in the 'developing'world. *Trends in pharmacological sciences, 31*(3), 99-101.
- World Health Organization (2004). *WHO medicines strategy: countries at the core: 2004-2007*: World Health Organization.
- Paul, S. M., Mytelka, D. S., Dunwiddie, C. T., Persinger, C. C., Munos, B. H., Lindborg, S. R., & Schacht, A. L. (2010). How to improve R&D productivity: the pharmaceutical industry's grand challenge. *Nature reviews Drug discovery, 9*(3), 203-214.
- Peters, D. H., Garg, A., Bloom, G., Walker, D. G., Brieger, W. R., & Hafizur Rahman, M. (2008). Poverty and access to health care in developing countries. *Annals of the New York Academy of Sciences, 1136*(1), 161-171.
- Schillinger, D., Grumbach, K., Piette, J., Wang, F., Osmond, D., Daher, C., . . . Bindman, A. B. (2002). Association of health literacy with diabetes outcomes. *Jama, 288*(4), 475-482.
- Taylor, D., & Al-Saeed, E. (2010). Can (and will) governments afford personalized medicine? *Personalized Medicine, 7*(5), 587-595.
- United Nations. (1948). *Universal declaration of human rights*.
- United Nations. (2008). *The Millennium Development Goals Report 2008*: United Nations Publications.
- Venable, J. M., Ma, Q., Ginter, P. M., & Duncan, W. J. (1993). The use of scenario analysis in local public health departments: alternative futures for strategic planning. *Public Health Reports, 108*(6), 701.