



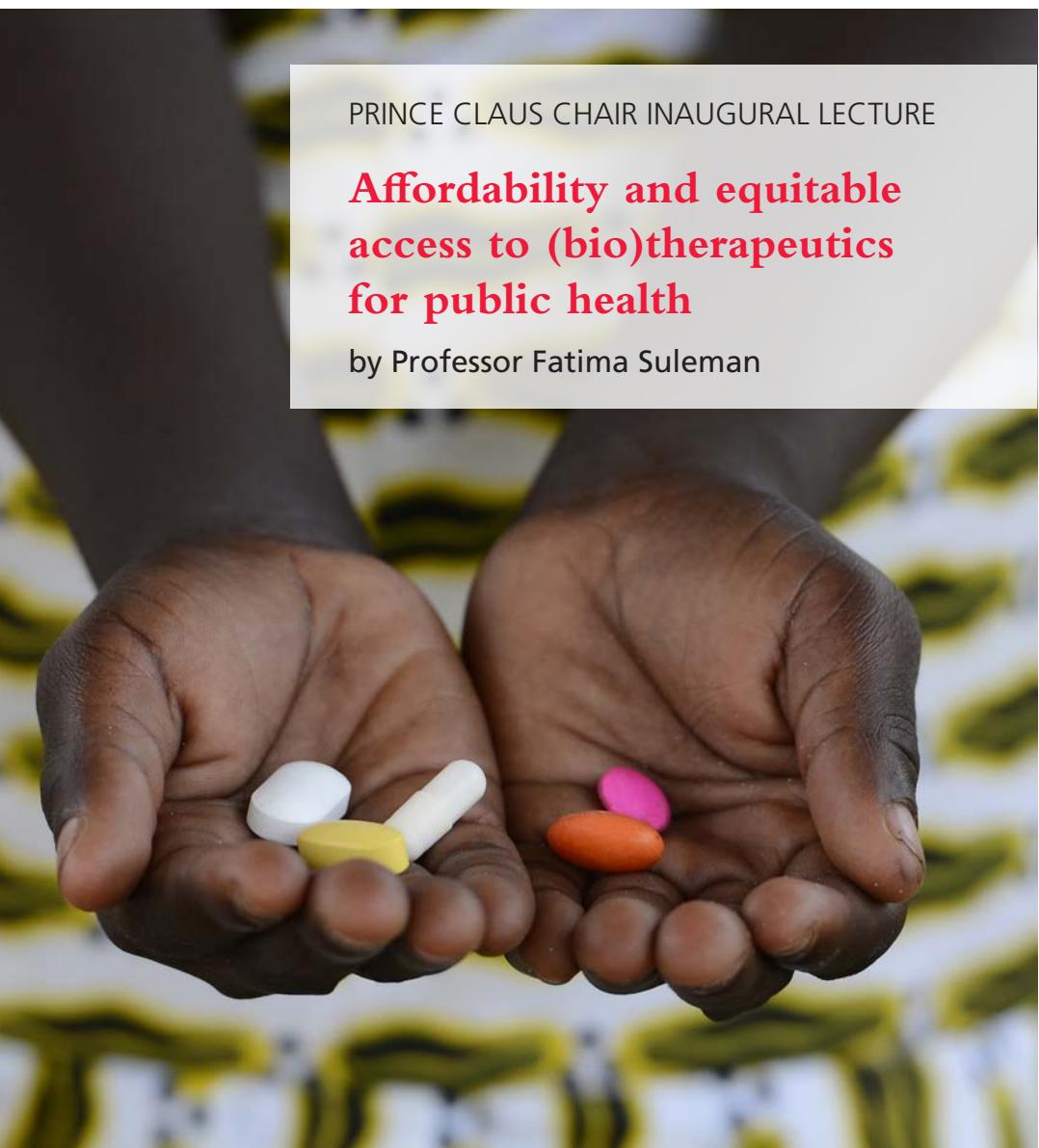
Utrecht University

Faculty of Science
Department of Pharmaceutical Sciences

PRINCE CLAUS CHAIR INAUGURAL LECTURE

**Affordability and equitable
access to (bio)therapeutics
for public health**

by Professor Fatima Suleman





Utrecht University

Affordability and equitable access to (bio)therapeutics for public health

Professor Fatima Suleman

Inaugural address as Professor to the Prince Claus Chair in
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Rector Magnificus, Members of the Curatorium of the Prince Claus Chair in Development and Equity, Excellencies, ladies and gentlemen,

It is my privilege to be here in this historic place and deliver my inaugural lecture, which is dedicated to the legacy of His Royal Highness Prince Claus and the extraordinary passion and effort he brought to issues of development and social justice. My lecture today centres around the topic of affordability and equitable access to medicines for public health. The United Nations High-Level Panel on Access to Medicines Report said:

*“Never in the past has our knowledge of science been so profound and the possibilities to treat all manner of diseases so great. ...And yet, many people and communities in need of effective prevention methods, life-enhancing and life-saving treatments and rehabilitation do not receive them. ...Availability, affordability and adaptation to specific settings and patient categories remain problematic in many regions and for populations throughout the world”.*¹

Let me introduce you to one such person from South Africa. Tobeka Daki was a single mother from Mdantsane township in South Africa who was diagnosed with breast cancer in 2013. Following her diagnosis, Tobeka was informed that she needed trastuzumab, in addition to a mastectomy and chemotherapy, to improve her chances of survival. A chance of survival that Tobeka was denied – not for medical reasons, but because she could not afford to buy it. Her cancer spread to her spine and on November 14, 2016 she died in her home. She did not get a chance to see her two sons and her grandson growing.

It cannot be said whether access to the medicine would have saved her. Yet, it did have the potential to improve her chances of survival. In South Africa, a 12-month course of trastuzumab costs approximately R516,700 (\$38,000) – or around five times the country’s average household income. It is unaffordable for even the government to provide in the public sector.

Medicines are a critical component for delivering key aspects of UHC, including coverage, service provision, and risk protection.² A family in Tanzania would, in most cases, spend 53% of family income on a child with type-1 diabetes. It is no surprise therefore that the Sustainable Development Goals (SDGs) adopted in September 2015, by the member states of the UN recognize that equitable access to affordable, quality-assured essential medicines is a crucial step in achieving universal health coverage.

Many low and middle-income countries (LMICs) have included the right to health, including access to medicines, in their national constitutions.³ However, this may not be enough to ensure or measure patient access.

A study by Cameron et al. found that the availability of 15 generic medicines used in the treatment of a number of conditions ranged from 38% in the public sector to 64% in the private sector.⁴ Another study by Van Mourik et al. found that overall availability of the five cardiovascular medicines was low, with an average availability of 57.3% in the private sector and 26.3% in the public sector.⁵

Many factors affect access to medicines, and aside from availability of medicines the next important factor is unaffordable medicine prices.⁶ Ensuring that medicines are, in fact, affordable is one dimension of access. Affordability becomes a particularly serious problem when medicines are needed for chronic conditions, including non-communicable diseases (NCDs).

But what do we mean by affordability of medicines?

Many countries have within their legislation, the need to ensure affordability of medicines to their population. In the determination of medicine prices, or even in the negotiation of medicine prices, the Minister of Health generally has to ensure that some form of affordability measure is considered. General economic measures of consumer price inflation, or medical inflation are sometimes considered. But is there a “true” measure of affordability? Is there a measure of affordability that can be quickly measured or calculated to inform policy directions?

There are different ways to define affordability, with assessments applied by researchers, typically focused on two levels: affordability for patients and/or households, and affordability for the health system itself. The WHO/Health Action International (HAI) Project on Medicine Prices Availability and Affordability measures patient affordability by estimating the number of daily wages (using the salary of the lowest-paid unskilled government worker) required to purchase a course of treatment.⁷

For example the cost of a monthly course of treatment with the lowest price generic for ranitidine was equal to 3 days of wages of the least paid government employee in the surveyed LMICs in Africa, eastern Mediterranean and Europe.⁹ In the private sector, chronic medicines costed between 1.3 and 19.6 days of minimum wage across a number of chronic conditions and countries.⁸

Affordability depends also on the budgets health systems can command to spend on medicines. Commonly-used indicators of health system spending on medicines include the proportion of total health expenditure on medicines, total pharmaceutical expenditure as a percentage of GDP, and per capita pharmaceutical expenditures.⁹ In LMICs, this data is not easy to access.

Affordability could be defined as a situation in which we consider something to be too expensive for someone (like a medicine). Another viewpoint could be that a person should at least be able to fulfill other basic needs after having purchased the good, which in this case is a medicine. Niëns et al¹¹ looked at affordability in terms of the proportion of the population being pushed below US\$1.25 or US\$2 per day poverty levels because of the purchase of medicines. This has the advantage that affordability becomes linked to the purchasing power of the people. So, what is affordable for people with an average income is probably not affordable for the poorest quintile.

However, to date, there is no easy and quick method of assessing affordability, and what is important to note is that affordability will differ from health system to health system, and from country to country. Thus far, the most popular measure is the previously mentioned WHO/HAI measures for patient affordability (by estimating the number of daily wages required to purchase a course of treatment). **We need to find more ways to measure affordability within a shorter timeframe, especially within a policy environment.**

At the health system level, there are no set benchmarks for what is an affordable medicine. **Can a LMIC health systems afford the medicines they put on their essential medicines list? Can they, for instance, afford a high-priced cancer treatment on their list?** These are questions that require urgent attention and research. In the next section I will describe why this is a universal issue for all countries by describing the trend of high prices for medicines.

In recent years, there have been a number of reports with regards to high cost medicines and medicine shortages. The price of medicines was one of the key election issues in the recent United States (US) Presidential election. Turing Pharmaceuticals raised the price of their medicine (pyrimethamine) by 5,455%, from \$13.50 (January 2015) to \$750 (August 2015). But Turing Pharmaceuticals is not the exception.

Merck's product sitagliptin used in the treatment of type 2 diabetes, went from \$146 in October 2006 to \$213 in December 2011, and by June 2016 it cost \$370 a month. This is a massive increase even if one adjusts for inflation. Norvatis raised the price of its oncology medicine imatinib, used to treat certain types of leukemia, from \$31,930 in 2001 to \$118,000 a year in 2015 despite a huge increase in the volumes sold.¹⁰

Several new innovative and orphan medicines that were approved by the Food and Drug Administration (FDA) entered the US pharmaceutical market with high prices. Biogen Idec's multiple sclerosis medicine, was priced at \$54,900 per patient per year; hepatitis C cures from Gilead Sciences, had a price of \$84,000 per patient; and a cystic fibrosis drug from Vertex Pharmaceuticals was priced at \$259,000 per year.

According to a Forbes report,¹¹ for 222 generic medicine groups, prices increased by 100 percent or more between 2013 and 2014. Generic medicines have for a long time now, been used as a mechanism to reduce medicine expenditure by payers and governments alike. Therefore, rising prices in generics like Mylan's albuterol sulfate (which increased about 4,000 percent from 2013 to 2014) are concerning. The increase in medicine costs, which were projected to be 12.6 percent in 2014, far outpaced inflation, which was between zero and 2 percent over the previous three years; medicine-related inflation had also outstripped growth in other medical costs.

It is therefore no surprise, that high price medicines are becoming the focus of US Congressional hearings as well as litigations. Class-action attorney Steve Berman is now pursuing cases against the pharmaceutical industry. He is accusing Sanofi, Lilly, and Novo Nordisk of raising the prices of their insulins by more than 160 percent over five years, leaving some patients paying nearly \$900 a month. He further alleges that the cost of an EpiPen auto-injector, which can be lifesaving for patients, rose by 500 percent over the last decade.¹²

This issue is not unique to the US. The topic of access to medicines has been debated by the European Parliament in plenary session in 2014 and 2015.¹³ The last session focused on the very high prices for certain life-saving medicines (e.g. sofosbuvir, a treatment against hepatitis C, and certain cancer drugs). It also raised questions about the rationale behind prices and the transparency thereof.

In Germany, health insurers are looking for ways to manage the high prices of new medicines, with some support from the government. The German government is planning to curb companies' liberty in setting launch prices. The head of the UK evaluation agency, NICE, has challenged pharmaceutical firms to show more restraint in pricing, or face price cuts. The head of Italy's competition authority has urged EU action to control medicine prices. Belgium, the Netherlands and Luxembourg are now working together to seek a common approach to their negotiations with drug firms. A commentary authored by the Dutch Minister of Health Edith Schippers in *The Lancet* stated that:

“The current pharmaceutical system is out-of-balance”, and “It is time to set a new course.” “We should take measures to better control the price of medicines.”¹⁴

The situation is the same, if not worse in LMICs. In May 2016, the Colombian government announced that it was giving pharmaceutical giant Novartis a few weeks to lower prices on imatinib (a cancer medicine) or see its monopoly on production of the medicine broken and competition thrown open to generic rivals. Colombia's health care system guarantees patients' access to all approved medicines. In 2009, the government declared a public health emergency after spending on sophisticated medicines had risen tenfold in just a few years.¹⁵

In fact, high cost and poor availability of cancer treatment are significant barriers to access in many LMICs. In Pakistan, which has a per capita income of \$2,860 dollars, the cost of treating leukemia with chemotherapy and associated transfusion requirements is \$20,000.¹⁶

In many LMICs, as many as 90% of people purchase medicines through out-of-pocket payments,¹⁷ and thus medicines are the largest family expense item after food. Research is necessary to look at what strategies are being employed by families to manage their expenditure on medicines, especially medicines for non-communicable chronic diseases, and how much is out of pocket spending. Are they being pushed into poverty? Is unaffordability compromising rational use of the medicine? Is unaffordability resulting in poor patient prognosis and therefore further healthcare expenditure?

Some preliminary work out of Tanzania on how people cope with insulin prices, indicates that 21% is financed OOP, 13% from support NGO, 35% commercial loan, 23% family loan, and 5% sell property. Often the child does not get the second dose in the day to save on the insulin required.

Governments and payers have tried to introduce interventions to manage medicine prices. In the next section, further description will be provided on what is being done to manage medicine prices across the world.

The past ten years have seen the introduction of several initiatives at both global and regional levels to support countries in managing pharmaceutical prices. In 2011, The WHO Department of Essential Medicines and Health Products led the development of a guideline on Country Pharmaceutical Pricing Policies.¹⁸ The guide looked at what price control measures could be used to manage medicine prices. The options include health technology assessment, and external reference pricing. In addition, the guide considered what measures could be adopted to control add-on costs in the supply chain and how countries could promote the use of quality assured generic medicines as a strategy to manage medicine prices. These are some of the most important recommendations from the guide:

- Different pricing policies need to be combined; one policy alone will not work
- Pricing policies must be transparent and supported by clear legislation
- The policies must promote the use of generics whenever possible
- Countries should collaborate and exchange information on pricing

The selection and implementation of all these pricing policies must take account of the wider health and pharmaceutical structure. Despite the best intentions, they may also have negative consequences. Let us take a closer look at what happened in South Africa.

In 1994, South Africa (SA) had seen the end of apartheid. A racially-motivated and discriminatory regime had resulted in a healthcare system grappling with a high

disease burden and facing several economic challenges, many of which still persist today.¹⁹ The high price of medicines in a previously largely unregulated medicines market posed one of the most important problems. South Africa's response to the pricing issue was the development of the National Drugs Policy (NDP) for SA to address the health, economic and national development objectives for the country. The policy document called for the establishment of a Pricing Committee committed to "*total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals*".²⁰

The introduction of government medicine pricing interventions was aimed at reducing the prices of medicines and controlling the mark-ups along the entire supply chain. Interventions that were introduced included the banning of discounts and rebates in the pharmaceutical sector; mandatory offering of generic substitution; the application of a Single Exit Price (SEP) from manufacturers and a separate dispensing fee for dispensers.^{21 22 23}

When the single exit price (which includes the logistic fee and value added tax), was first introduced in 2004, it was a compromise from the initial government intention to force a 50% reduction in prices. The method used to determine the maximal annual adjustment of the single exit price policy included looking at an industry supported formula (based, for example, on consumer price inflation and the exchange rate between the local currency and major global currency), but the regulations allowed the Minister of Health to take other aspects into consideration (including affordability). At times, the adjustments were capped at the level of the prevailing consumer price inflation rate, but they have varied widely, from a zero adjustment in 2011 to a high of 13.2% in 2009.²⁴

There have been no published studies evaluating the impact of the SEP on medicine prices. Some indication of the impact of the medicine pricing policies over time can be indirectly assessed in terms of the contribution of the cost of medicines to total medical scheme expenditures as reported in the annual reports of the Council for Medical Schemes.²⁵ In contrast to the increases in expenditure on private hospitals and medical specialists, expenditures on all other health professionals (general practitioners, dental specialists, dentists and other supplementary and allied health professionals) have remained relatively constant. Expenditures on medicines declined after 2003 reaching a low in 2005, after adjustment for inflation.²² This could be related to the introduction of mandatory offer of generic substitution in 2003 and the introduction of SEP in 2005.

However, by 2009, expenditures in constant Rands (ZAR) had rebounded to the same level as 2001 and have continued to increase.²² The largest of the medical scheme administrators has estimated that the introduction of the single exit price mechanism resulted in an approximately 22% reduction in medicine prices and saved the scheme about ZAR319 million per year in medicine expenditure since 2004.²⁶

Analyses from an ongoing study into the impact of the introduction of the SEP on medicine prices, indicate that in the main, prices have remained low, but there was no significant difference between projected prices in an unregulated market versus and the regulated SEP prices. In fact, in some cases, prices increased or remained constant, rather than decreased as projected.

In addition, Mediscor's most recent medicines review found the difference in price between an originator medicine in South Africa and the average-priced generic alternative in SA was 45.2%, and that generics accounted for 53.6%–65% of the volume of medicines sold in SA.²⁷ So if other countries want to emulate South Africa's pricing interventions, we have no evidence to support our claim that it works!

To address the increase in medicine prices, as well as the perceived high prices of medicines within South Africa, a number of elements of the pricing system are still evolving through discussion with various stakeholders in SA. In my capacity as Chair of the Pricing Committee, I have been involved in these policy debates, and have been privy to the strong resistance from the industry and the need to employ delicate, or what I term, “soft” negotiating skills.

The logistics fee, which is the fee paid to distributors or wholesalers to move a product through the supply chain, is presently not disclosed by manufacturers and the extent of the logistics fee is not regulated in any way.²⁸ Proposals in that regard have been made, but as yet not implemented. Determination of an appropriate logistics fee is still a debatable issue among the various stakeholders. A key contentious issue is the definition of a bonus system, a rebate system, or any other incentive scheme and “discounts”. The ban on off-invoice bonuses, rebates and various other marketing incentives has been difficult to enforce, and a draft set of definitions of such practices in regulations has been published for comment, but not yet finalised.²⁹

Since 2013, although guidelines for the submission of pharmacoeconomic evaluations of new medicines, justifying their initial single exit prices, have been

available, such submissions have remained voluntary.³⁰ There is still uncertainty among pharmaceutical industry stakeholders that there is enough capacity in the country to generate applications and to evaluate these applications.

The planned introduction of external reference pricing referred to locally as international benchmarking has also not been finalised.³¹ The initial basket of comparator countries includes Australia, Canada, New Zealand and Spain. Both of the latter policy interventions have faced great opposition from the pharmaceutical industry in South Africa. The Pricing Committee and the National Department of Health have developed systems and opportunities to engage stakeholders in policy discussions, and negotiate through disagreements, but these are experiences that are not reported, and are therefore not accessible to other countries going through the policy development and implementation process. More research needs to be done in this opaque” area of implementing policy without undue legal wrangling. Questions should also be raised as to whether these negotiations are open to all or are limited to a policy elite? Is this also a mechanism to avoid litigation?

Finally, it is not clear more than 10 years after all of these pricing policy interventions what the impact has been on access and affordability of medicines to people in South Africa. The knowledge and views of patients with regards to pricing policies is largely unknown. As a Chair of the Committee tasked with creating transparency in medicine pricing, this omission is of great discomfort to me personally.

A PhD study I supervised, was conducted in eThekweni, Durban, South Africa from September – November 2016. Focus group discussions were held with 8 groups of parents’ and guardians from different areas in eThekweni, and found that irrespective of the socio-economic level, all participants were of the opinion that medicines were indeed expensive, although considered affordable by the middle class and affluent groups:

“Why is medicine overpriced because it’s not a luxury; it’s a necessity for people. So why is it so overpriced?” Middle class Parent

South Africa did achieve some success with regards to improving access and reducing prices of anti-retroviral therapies (ART). With the assistance of civil society and patient advocates, most notably the Treatment Action Campaign (TAC), the issue of high priced ART was brought to the attention of the South African public.

TAC aimed to widen access to anti-retroviral drugs for prevention of mother to child transmission (MTCT), post-exposure prophylaxis following sexual assault and

for use in combination drug therapy. The new, powerful, and very expensive HIV treatment worked by suppressing viral replication and allowing for immune system recovery. This scientific breakthrough, which was announced in 1996, changed HIV from a relentlessly terminal illness to a manageable chronic condition in the wealthy Northern countries. However, the pharmaceutical industry kept the price of these medicines unaffordable in developing countries in the South with a high HIV prevalence, such as South Africa, by insisting on exercising their patent monopolies.

In 2001, the Pharmaceutical Manufacturers Association, representing 47 multinational pharmaceutical companies, took the South African government to court to block the implementation of the Medicines and Related Substances Control Amendment Act of 1997. At the time, it was assumed to enable compulsory licensing by the MOH (regardless of the Patents Act), but it was subsequently interpreted to only allow for parallel importation (which has never been used) in South Africa.

TAC supported the government in the case, acting as ‘friend of the court’, by helping to mobilise local and international activist support and global public opinion in favour of the government. Due to international public pressure and the negative perceptions the case generated about the pharmaceutical industry, the case was dropped (but only after three years). This case resulted in the postponement of the implementation of medicines legislation and cost the South African tax payer a lot of money. It also made the Government wary of court battles and litigation.

TAC subsequently successfully pursued action against the transnational industry, by alleging abuse of patent monopolies to inflate prices, but using competition (antitrust) law, rather than patent legislation. The targeted manufacturers were GlaxoSmithKline (which produced the antiretrovirals zidovudine and lamivudine) and Boehringer Ingelheim (which produced nevirapine).

However, aside from this case, which was decided without a final finding by the Competition authorities, very little attention has been paid to investigating the impact of patient protests on high price medicines on reducing medicine prices and eventually on patient access and affordability. In addition, how transparent are the pricing interventions to patients and do they see the benefits of these interventions, as they are the intended beneficiaries or are there other mechanisms employed by the industry to retain income from medicines?

South Africa is not alone in trying to manage medicine prices. Europe has tried to introduce pricing policies as well.

European countries have developed a variety of pricing and reimbursement policies. The aim was to ensure affordable access to medicines, and to protect the population from financial hardship. Another aim was to contain the costs and save public funds. Residents in most European countries benefit from comprehensive coverage of healthcare costs. This includes the costs related to medicines.³²

A large portion of the spending on medicines comes from public programmes. Yet there is considerable variation in public funding on medicines and in access to medicines between countries.³³ There are many possible reasons for these differences. It could be due to different marketing of medicines, or to their inclusion in national reimbursement lists. It could also depend on the country's gross domestic product, government expenditure on health, or medicine prices and use.

In Europe, decisions about reimbursement of medicines are taken at the national level. Patients usually have to contribute to the costs of outpatient medicines; however, various mechanisms exist to protect patients from excessive out-of-pocket payments.^{xxxvi} In some countries, health technology assessment (HTA) is used to inform reimbursement or pricing decisions (e.g. France, Italy, the Czech Republic, Switzerland).

Most European countries refer to the price in other countries to set the price of medicines in their own country, a practice known as external price referencing (EPR). However, the scope, relevance and methodological design vary across countries. In Denmark, for instance, EPR only applies in the hospital sector. In Germany, EPR exists in the legislation but is not used in practice.³⁴ This international price comparison offers a reference, or benchmark, for policy-makers, to understand where the prices proposed by the pharmaceutical industry for their country are relatively ranked.

EPR has had some unintended consequences. It has been argued that public payers could keep a high 'list price' and get confidential discounts through product specific agreements.^{35 36} Confidential discounts and rebates are blurring the price transparency of the market, and they limit the ability of payers to determine what a '*reasonable and fair*' price would be.

Another policy, viz. generic policies are considered as a valuable instrument to generate savings for public payers that can be used to afford more expensive medicines and treat more patients. European countries use a mix of policies related to pricing, reimbursement and enhancement of uptake of generics.

Twenty-two EU member states (as of 2016) use ‘*internal reference pricing*’, i.e. maximum reimbursement amounts for clusters of medicines. In nine of these countries, clusters of medicines with the same active ingredient have been established, while in 13 countries a reference price is applied to therapeutic substitutes, i.e. substitution between medicines which are not chemically the same, but have largely the same clinical effect and safety. (e.g. Germany and The Netherlands).³⁷ Most EU member states set the price of generics in relation to originator prices, whereas fewer countries (e.g. Finland, Germany, Norway, Sweden and the UK) exclusively rely on competition.³⁸

It is evident from both the South African case and the description of policies implemented in Europe, that there is not enough evidence with regards to which of the policies, or combination of policies, best achieves their intended objectives, and minimizes unintended consequences. There is a need to document both the successes and the difficulties in implementing pricing policies across countries over time. This brings us to the concept of transparency.

“Recognizing that data on medicines lie in a fragmented manner across a health system – and that information is central to a systems approach to medicines – there is an urgent need to develop innovative means for generating information from data and for connecting not only information on medicines policies, but on the actors who gather, shape, control and make decisions based upon that information”. (Bigdeli, et al)³⁹

Fundamentally, the objective of attaining price transparency is to obtain accurate price information to assist policymakers and researchers and empower buyers to negotiate more strategically. This is to hold pharmaceutical firms more accountable for prices.⁴⁰ Price transparency can provide accurate information to governments and payers.

Also, transparency in pricing can expose irregular price mark-ups, it can assist in the avoidance of drug shortages through accurately forecasting quantities of essential medicines. Theoretically, increasing price transparency has the potential to increase accessibility to drugs – both in terms of decreased prices and greater availability.

Most of the arguments that have revolved around transparency in medicine pricing have concentrated in two key areas: transparency in research and development costs by pharmaceutical manufacturers, and in disclosure of pricing arrangements by governments and payers.

Pharmaceutical companies state that they need to recoup its investment in the clinical studies it designed to bring a medicine to market. It has been reported that less than 10% of new drugs make it through clinical trials and are ultimately approved.⁴¹ In August, Harvard researchers found that the 10 largest pharmaceutical companies spent between 7% and 21% of total sales on research and development.⁴² Much more is spent on marketing and on profit gain. There is a lack of evidence on the effects of price transparency in reducing medicine prices and this needs to be improved.

In addition, very little has been done in the area of transparency for patients. A national database on medicine prices within and across therapeutic classes would make medicine prices more transparent for patients. It is an important information gathering tool for patients who want to compare prices so they can make more informed decisions about their medicines.

Most people would want greater price transparency and would compare medicine prices across and within therapeutic groups if given the option. In addition, routine collection of data on the actual prices paid by patients for medicines rarely occurs, especially in settings in which out-of-pocket payments are common and the prices paid are highly variable.

What would need to be monitored is if transparency actually lowers the cost of medicines and/or health care? There is also a need to relook at how research and development of medicines can be funded.

At present a traditional business model exists for medicine research and development (R&D), and pharmaceutical companies are profit driven, having to account to their investors and shareholders. However, increasingly, there are academic-industry partnerships that work together in biotherapeutic research. In many cases, funding for the earlier work (or some part of the work), is done at universities and comes from government agencies or from public funds.

As is the case with making research that is publicly funded open access and available, **should these medicines then not be priced to make these medicines more affordable?** There is a need for studies to look at alternate models to fund R&D. The Global Funds, through UNITAID, receives some of its funds from airline taxes or levies. **Is it not possible to implement a similar approach for a fund for medicines R&D? Can proposed taxes on sugar and salt use in foods and beverages not be directed (even as a small percentage) towards a fund for medicines R&D?**

If we continue with the current business model that industry research is funded through high medicine prices after the discovery has been made, discussions would then need to revolve around what a “fair” price for a medicine would be, so as to maintain research and development and supply, and not create shortages or market withdrawal. What constitutes a “fair” price? **What are the components that need to be considered in the determination of a “fair” price? Should this differ between countries according to income of the people in those countries?**

Medicine price discussions should focus on the “reasonable bounds” of pricing, and the price of a new essential medication should reflect how much it advances the practice of medicine and how it can achieve universal access as soon as possible.

Let me now summarize my arguments

When we try to understand access to medicines through a health systems approach, we must take into account several other factors. First, **studying the effect of a certain intervention over time is important** because in complex systems the people and the system adapt. For example, an intervention may have a so-called “flash effect” – it looks successful immediately but is less so in the medium and longer term. In complex systems, multiple actors each have their own perspectives and their own ways to influence each other’s behaviour. When assessing an intervention in a complex system, we must attempt to **predict such behaviour, as these reactions may have unintended consequences**. Identifying potential unintended effects before an intervention is implemented is very important – otherwise unintended outcomes may overshadow the good intentions. I think it is very needed that both the successes and the difficulties in implementing pricing policies across countries are recorded over longer periods of time.

These are some of the areas of research that I would like to explore in my tenure. **Which quick measure of affordability can be used by policymakers to assess the affordability of medicines for the population? Can a health system in a low- or middle income country afford the medicines they put on their essential medicines list?**

I would also like to initiate research in the strategies that families use to manage their expenditure on medicines, especially medicines for non-communicable chronic diseases. **How much do they receive from the system, how much do they spend out-of-pocket, and what other coping mechanisms do they have? How transparent are pricing interventions to patients and do they see the benefits of these interventions, as they are the intended beneficiaries?**

This work may continue beyond the period of the Chair, but with the networks that are being formed, I am hopeful that these will be addressed in the next 5 years.

I cannot conclude my lecture without expressing my sincere **thanks and appreciation** to the Curatorium of the Prince Claus Chair for their nomination.

My special thanks are due to Utrecht University and its Executive Board for the honour bestowed upon me by this appointment. I would also like to specially acknowledge Dr Aukje Mantel-Teeuwisse, Prof Bert. Leufkens, and Dr Rianne van den Ham, Department of Pharmaceutical Sciences who initially put my name forward, and all the staff of the Department for the warm welcome and continuous

support they have given me. The short time I have already spent at the Department has been a pleasure and a privilege and I am looking forward to our continued collaboration. I wish to thank Prof Ellen Moors, from Innovation Studies for her support, advice and assistance thus far. I will always remember her sneaky method of interviewing me for this nomination.

There are a number of people who have had an influence in my career and my life along the way. I wish to acknowledge the influence of the following: Hans Hogerzeil, David Henry, Sue Hill, David Harrison, Jennifer Smit, Andy Gray, Sabiha Essack, and my postgraduate supervisors: Prof Cassim Mohamed Dangor and Prof Edward Mensah, as well as a Fulbright administrator who had faith in me: Monica Joyi.

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I want you all to know that these accomplishments are your accomplishments too, for you have all played a role in getting me here today. Who would have thought that a child born, brought up and educated under an apartheid regime would end up here today?

Thank you!

Notes

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**“Access to biotherapeutics
is part of the fulfillment of
the right to health.”**

Professor Fatima Suleman

The Prince Claus Chair in Development and Equity was established by Utrecht University and the International Institute of Social Studies of Erasmus University Rotterdam, and rotates annually between the two institutions. Fatima Suleman has been appointed as the holder of the Prince Claus Chair 2016-2018.

Fatima Suleman, associate professor of Pharmaceutical Sciences at the University of KwaZulu-Natal in South Africa, has been appointed to the Prince Claus Chair of Development and Equity as of 1 September 2016. During her two year term, she will be conducting research into affordable (bio)therapeutics in collaboration with scholars at Utrecht University, other scholars in the Netherlands and the World Health Organization (WHO).

In addition to her appointment to the University of KwaZulu-Natal, Fatima Suleman also has ties with Drake University in the United States. She is interested in equity and access to medicines, pricing and reimbursement policies and essential medicines, especially for chronic conditions which cause huge suffering. Fatima Suleman is the Chair of the National Pricing Committee for Medicines in South Africa and has taken part in various international committees on drug pricing including an informal panel at WHO on Fair pricing. In addition she is a member of the WHO Expert Committee on the Selection and Use of Essential Medicines.