



# THE LANCET YOUTH COMMISSION ON ESSENTIAL MEDICINES POLICIES REPORT

## Towards Realising Access to Essential Medicines for All : A Vision for 2035



I. Promoting Consensus and Accountability:  
towards a New Vision  
for Essential Medicine Lists



II. Enabling Global Reform, Cooperation,  
and Consensus to Ensure Access  
to Essential Medicines



III. Supporting Regional and Multilateral  
Cooperation to Achieve Accessibility,  
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of Essential Medicines



IV. Translating Essential Medicines  
Policies into Practice at Country Level

# **Towards Realising Access to Essential Medicines for All : A Vision for 2035**

**The Lancet Youth Commission on Essential Medicines Policies**

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## About the Commission

The Lancet Youth Commission on Essential Medicines policies was formed in March 2015 in response to the launch of The Lancet Commission on Essential Medicines Policies, to introduce a vital youth perspective into consideration and framing of essential medicines policies looking towards 2035.

The Lancet Youth Commission on Essential Medicines Policies (YCEMP) is composed of 17 Commissioners selected from every region in the world, with diverse professional backgrounds and experiences.

All authors contributed to the commission in their individual capacity. The views expressed by the Youth Commission are those of the authors alone, and do not reflect the views of the organizations with which commissioners are affiliated.

The Youth Commission has provided welcome comment on The Lancet Commission on Essential Medicines report, which was published 8th November 2016.

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All conflicts of interest in relation to this report have been declared in accordance with World Health Organization guidelines; details are available on request.

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## INTRODUCTION : THE FUTURE OF ESSENTIAL MEDICINES POLICIES

In 1977, the WHO published its first Model List of Essential Medicines (EML) in response to Member States requesting guidance regarding selection and procurement of medicines in resource-constrained environments. The list, which illustrated how to implement the concept of “essential medicines”, was devised primarily as a tool to assist low- and middle-income countries (LMICs) to identify and select medicines with proven safety and efficacy that met the priority healthcare needs of the population (WHO 1977).

Creation of the WHO EML helped establish a global understanding that access to certain medications that met the health needs of the majority of a given population should be prioritised (See Box I.I for “Definition of Essential Medicines” according to the WHO).

Despite significant international efforts to improve access, however, essential medicines remain inaccessible for many people worldwide. For example, the mean availability of existing essential medicines in 27 low- and middle-income countries where data is available has been measured at 38.4% in public facilities, and 64.2% in private facilities (Cameron et al. 2009). There are also significant issues concerning creation of new essential medicines: the majority of medicines developed worldwide cater to patients in high-income countries (HICs), with research indicating that 85-90% of new medicines developed since the mid-1990s have little or no added therapeutic value compared to current treatment options (Light and Lexchin 2012; van Luijn et al. 2010; Vitry et al. 2013; Morgan et al. 2005; Kaitin et al. 1991).

### **Box I.I: Definition of Essential Medicines**

*'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. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.'* (WHO 2003)

Essential medicines are also frequently unaffordable for patients, particularly in LMICs, where out-of-pocket (OOP) payments constitute a significant proportion of healthcare expenditure. Significant proportions of healthcare budgets in LMICs and HICs are spent on pharmaceuticals, primarily due to high prices and irrational use (Kanavos et al. 2010; Hogerzeil 1995). Moreover, prices vary significantly between countries, even taking into account purchasing power parity. The WHO targets that consumer should not pay more than four times the MSH international reference prices (IRPs). The lowest-priced generic medicines in low- and lower-middle-income countries are, on average, 2.9 times the IRPs in public sector facilities, and 4.6 times higher in private sector facilities (UN 2015). In United States (Boston area, Massachusetts), the lowest-priced generic versions were priced substantially higher at 11.5 and 38.0 times the IRPs, respectively, for the over-the-counter and prescription medicines (Sharma et al. 2016).

Where new, lifesaving drugs are developed, financial accessibility is significantly constrained by the current pharmaceutical patent system, globally exported through implementation of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS). This agreement's patent protection requirements can lead to medicines being priced far too highly for the average person to afford, especially in LMICs--but increasingly in HICs as well (Hellerstein 2011). Although it is important for innovators to benefit from their inventions, the application of a patent protection period can be at the expense of individual lives.

In summary, significant barriers exist to achieving equitable and affordable access to essential medicines, despite WHO and the international community's decades-long recognition of that certain medicines should be prioritized for public

health. It is encouraging, however, that increasing international attention and political priority is currently being given to essential medicines; most notably, through the Sustainable Development Agenda, and the United Nations High Level Panel on Access to Medicines (UNHLP 2016).

### ***Sustainable Development Goals and access to medicines***

Ensuring access to essential medicines is critical to reach Sustainable Development Goal (SDG) 3, which calls for global action by Member States and stakeholders to achieve universal healthcare coverage, including "access to safe, effective, quality and affordable essential medicines and vaccines for all". To ensure sustainable access to medicines, it is also necessary give emphasis on another SDG target: how to "promote research, development, innovation and increase access to medicines, vaccines, diagnostics and related health technologies to improve the health and wellbeing of all". (see Box I.II. SDG 3. Ensure healthy lives and promote well-being for all at all ages)

This SDG target is specifically stated to be achieved in accordance with the Doha Declaration on TRIPS and Public Health, which affirms the right of all governments to fully utilize so-called TRIPS flexibilities, which include voluntary and compulsory licensing and parallel importation to protect public health (discussed in Chapter III).

Although we agree that this should occur, our vision for 2035 exceeds temporary solutions to existing agreements and practices, and involves new health innovation and medicines delivery systems that, above all, responds to public health needs. Through this document, we hope to advance a more novel agenda, and to explore methods through which access to essential medicines can be secured for all.

### **Box I.II. SDG 3. Ensure healthy lives and promote well-being for all at all ages**

Target 3.8. Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all

Target 3.b. Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all

### ***The role of the Youth Commission in advancing the access agenda***

The Lancet Youth Commission on Essential Medicines Policies (YCEMP) was convened in March 2015 after a group of students from the student organisation Universities Allied for Essential Medicines (UAEM) proposed to examine essential medicines policies from a youth perspective. YCEMP, established through a transparent and open process, is comprised of 17 young professionals from 15 different countries, representing every region in the world.

We argue that if essential drugs are not made available to all people in need, the essential medicines concept does not realise its full potential. This holds true from both a public health and a human rights perspective, considering the obligations of Member States under the right to health, and the right to science and culture, as outlined in the United Nations Covenant on Economic, Social and Cultural Rights. Although limitations in accessing medicines have received attention from a variety of actors and institutions for decades, many essential medicines are still not available, affordable or accessible for all those in need. We believe that new approaches are

required: the current system is inadequate, and fundamentally new models of medicine creation, production and distribution are needed. As young people in the early years of our careers in the field of access to essential medicines, we are less bound by existing structures, institutions and ideas. We seek to challenge the *status quo* and hope to bring a fresh perspective to this area.

In particular, YCEMP seeks to ensure that deliberations around, and measures proposed for, improved essential medicines policies through the Sustainable Development Agenda and the UNHLP are not strongly bound to existing institutions and practices. For example, we argue that sufficient gains have not been made in securing access to medicines through iterative changes to present structures, such as the [Trade-Related Aspects of Intellectual Property Rights](#) (TRIPS), or through existing incentives for research and development (R&D), so entirely new systems and processes should be considered.



### **Key principles underpinning the work of YCEMP**

As young professionals, we highlight the following key principles that frame our recommendations and will be, in our view, cornerstones of effective essential medicines policies over the next 20 years (See Box I.III).

#### **Box. I.III. Key principles underpinning the work of YCEMP**

- ◆ A global vision: essential medicines for all countries, as a shared global challenge and responsibility
- ◆ Human rights and equity: access to essential medicines and scientific progress as basic rights
- ◆ Knowledge sharing and innovation: research and development as global public goods
- ◆ Future-oriented: a vision for essential medicines based on expected future challenges and opportunities
- ◆ Sustainable development: essential medicines are crucial to deliver on the SDGs and UHC
- ◆ Accountability: a call to all stakeholders, particularly decision-makers, to deliver on ensuring access to essential medicines

#### *A global vision: essential medicines for all countries, as a shared global challenge and responsibility*

Historically, access to medicines has been predominantly viewed as a problem experienced in resource-constrained settings. Moving towards 2035, however, if active steps are not taken to implement sustainable and effective essential medicines policies, people living in all countries will increasingly face challenges in accessing medications. State governments will increasingly

encounter two core difficulties in ensuring delivery of healthcare services to their population.

First, rising burdens of illness worldwide, particularly of noncommunicable diseases, will contribute to increases in demand for medications across larger populations, for longer periods of time. The high price of medicines remains a disproportionate burden on patients and health systems in low- and middle-income countries (LMICs). However, securing access to medicines is increasingly becoming a global challenge (Iyengar et al. 2016). Inaccessible pricing of medicines such as direct-acting antivirals (DAAs) (for hepatitis C), insulins (for diabetes), and epinephrine (for anaphylaxis) affects patients in all countries, signaling more clearly than ever before that the world can no longer afford inaction.

Secondly, fluctuations in economic prosperity, together with increased interconnectedness in global financial systems, have significant impacts on access. The global financial crisis of 2008 forced many previously affluent countries to face significant budgetary constraints (Vogler et al. 2015), the effects of which may still be felt over the coming years. In addition to unexpectant changes in the global economy, the financial difficulties in paying for patented drugs may increase. An increasing number of new medicines are being, or will be, developed over the next two decades. Together with a trend toward more targeted therapies and biopharmaceuticals, this will further strain already limited healthcare budgets (Vogler et al. 2015).

The factors above will require governments to set priorities on how funds are allocated, make difficult trade-offs, and secure the lowest possible prices for essential medicines in order to serve the public. Decisions will be needed on which patient groups should be served, which medications should be made available, and to what extent medications should be provided at a subsidised cost or for free. Accordingly, obtaining low prices for medications will become vital for all countries to create



budgetary space for provision of other priority health services. For example, the prices of a selection of relevant medications in Australia are between six to twenty times higher than in neighbouring New Zealand (Duckett 2013). In a setting of healthcare expenditure limitations, this is a situation that national health systems will be progressively less prepared to tolerate. Therefore, the concept of essential medicines will become increasingly relevant to HICs facing new resource challenges, while continuing to be critical to LMICs.

*Human rights and equity: access to essential medicines and scientific progress as basic rights*

The United Nations Covenant on Economic, Social and Cultural Rights (UNCESCR) identifies access to essential medicines as a human right, both through the right to health (Article 12) and the right to benefit from scientific progress (Article 15). Pursuant to Article 12, healthcare goods, services and facilities - including essential medicines - must be available, acceptable, accessible and of good quality.

Although the UNCESCR also provides for innovators to be able to benefit from the protection of the moral and material interests resulting from any scientific, literary, or artistic production (Article 15), this must be fairly balanced with the other rights in the covenant. YCEMP believes that, over the past few decades, increased protection of innovator rights has occurred at the expense of the health rights of many people. It is clear from General Comment No. 14 that provision of essential medicines, in accordance with the WHO Programme on essential medicines, is a core obligation under the right to health. Steps must be taken to more fairly balance these rights in international instruments and domestic law.

*Knowledge sharing and innovation: research and development as global public goods*

YCEMP believes that scientific progress and knowledge should be acknowledged as global public goods. This has significant implications for the current R&D system, which places a disproportionate emphasis on the rights of those who bring drugs to market through intellectual property protections. This system only incentivises the production of medicines, which are profitable rather than of public health relevance.

Although those who develop drugs should benefit from their innovation, this should not be at the expense of human lives. The world can no longer tolerate a situation wherein the majority of the world does not have the opportunity to benefit from these developments, and we believe that reform of both innovator protections and R&D systems around pharmaceuticals are urgently required.

*Future-oriented: a vision for essential medicines based on expected future challenges and opportunities*

YCEMP argues that, in considering access to medicines, we have to look beyond one or five year plans. While we welcome existing efforts, intersectoral collaboration will be needed to address the challenges we anticipate.

Access to medicines debate must acknowledge global challenges outside the health sector. Sociopolitical and environmental factors will continue to influence how people live and interact, also shaping the demand and supply of medications. Conflicts, large scale migrations, natural disasters, and occupational diseases can no longer be considered unexpected events for which health systems do not need to be prepared. Furthermore, economic inequality within and among countries must be addressed. However, these challenges could be balanced by

opportunities that potentially can improve access to medication, and population health. Investing in people's health - including medicines - has benefits in respect of development (Jamison et al. 2015). Equity and increased quality and coverage of health care delivery services, internet connectivity, citizen engagement, and medical innovation are intersecting processes that can collide to together to prevent disease and ensure treatment for all those who need it.

Furthermore, demographic and epidemiological changes will continue to influence the quantity and distribution of medicines needed. By 2035, the global population will increase to 8.7 billion, with an increasingly large elderly population. In sub-Saharan Africa, the population is expected to increase from 990 million in 2015 to 1.6 billion in 2035 (UN 2015). More people will live in cities than ever before; by 2045, 6 billion people worldwide will be urban residents (World Bank 2015). With an ageing population, the world will increasingly require treatment for people living with multiple chronic conditions. Noncommunicable diseases (NCDs), which already have an enormous morbidity and mortality footprint, represent a higher proportion of the global burden of disease (Wang et al. 2015). Infectious diseases may also emerge or re-emerge, and there is therefore a need to ensure better and faster development of medicines and vaccines (Jones 2008).

Finally, the rise of personalised medicine and growth in patients' expectations around medical treatments will bring increased complexity to healthcare, and challenge already-burdened health systems, especially those that are publicly financed; accordingly, steps will need to be taken to constrain or ration spending. This will be an enormous political challenge. In societies without public financing, however, the burden of out-of-pocket payments will fall on individuals. Unless financial protection systems are in place, we fear the high risk of catastrophic costs and

indebtedness incurred from purchasing medicines will continue.

We can either harness these changes and create *equitable* growth, including growth in the access to medicines space, or risk arriving at a deeply divided global setting in 2035, where technological advances and development have left many citizens behind. One important setting in which a dialogue around this topic is occurring is through the Sustainable Development Goals (SDGs).

*Sustainable development: essential medicines are crucial to deliver on the SDGs and UHC*

The SDGs provide a future “plan of action for people, planet and prosperity”. The MDGs shaped the development agenda from 2000 to 2015, and we expect that the SDGs will influence global discussions in the coming years. Several of the goals and targets involve essential medicines. Goal 3 on health is particularly relevant, with essential medicines included as target 3.8 on universal health coverage (UHC) and target 3.11 on R&D.

YCEMP wishes to see essential medicines policies as part of a broader sustainable development agenda, which should include participatory and transparent structures to allow for full and frank discussions around essential medicines selection, prequalification, procurement, and financing. Financial pressures on countries, payers, and individuals alike will only continue to grow.

*Accountability: a call to all stakeholders, particularly decision-makers, to deliver on ensuring access to essential medicines*

We argue that we have for too long accepted the access to medicines crisis. Current leaders in governments, pharmaceutical companies, academia, civil society, and multilateral agencies including WHO need to be held accountable for what they do - and do not - deliver. Measuring

progress towards the SDGs should include specific indicators to determine whether countries are delivering in ensuring access to essential medicines. We believe that failure to do so in 2016 is rooted in the lack of global and national accountability mechanisms.

In our report, we highlight how our recommendations are tied to these key principles.

Our recommendations are the result of analyses and deliberations on essential medicines by a geographically diverse and multidisciplinary group of students and young professionals. It is not a technical report, but instead an independent call to action *towards realising access to essential medicines for all*.



## I. Promoting Consensus and Accountability: towards a New Vision for Essential Medicine Lists

## I. PROMOTING CONSENSUS AND ACCOUNTABILITY: TOWARDS A NEW VISION FOR ESSENTIAL MEDICINE LISTS

**Recommendation 1.1: That all countries, irrespective of income levels, adopt National Essential Medicines Lists (NEMLs) which reflect population health needs and clinical best practices. These NEMLs should be separate from, and used in conjunction with, national medicine procurement and reimbursement lists and/or programs.**

The concept of essential medicines first received international attention in the 1970s when Dr. Halfdan Mahler, then Director-General of WHO, strongly advocated that UN Member States develop national pharmaceutical policies based on medicines affordability, availability, and quality (Greene 2010). Member States then called upon the WHO to assist countries in the selection and procurement of these essential medicines. The first Model List of Essential Medicines (later Essential Medicines List, EML) in 1977 has been described as “a peaceful revolution in global health” (Laing et al. 2003). Since then, 19 subsequent revisions to the WHO Model Essential Medicines List (WHO EML) have occurred in line with a shift in the global burden of disease, as well as the adoption of an evidence-based approach with the principle that addition or removal of a medicine from the list should be based on objective criteria such as public health importance, safety, efficacy, and comparative cost-effectiveness. Another important addition to the WHO EML was the Essential Medicines List for Children (EMLc) in 2007, as children require different medicines dosage, formulation, and delivery to adults (WHO 2011).

The WHO EML has significant normative importance: it sets global standards around the selection of priority medicines to be delivered to populations and provides evidence to guide countries in their decision-making for national prioritization. It is, however, arguably National Essential Medicines Lists (NEMLs) that have the most profound impact on access. In many

countries, the NEML also guides procurement and/or reimbursement decisions. Since the introduction of the WHO EML, a majority of countries have adopted a NEML (WHO 2016).

### WHO definition of essential medicines:

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.

Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

Over the years there have been many technical, logistical and political conflicts over which actors and criteria determine the medicines that are essential to the health of the public. While discrepancies between the WHO EML and national lists are expected due to variations in disease burden, for instance, there appears to be a global disagreement and lack of clarity regarding the purpose of EMLs, and their inclusion criteria. In particular, the inclusion of expensive, patented cancer and hepatitis drugs in the 2015 WHO EML prompted extensive debate (Manikandan 2015). Stakeholders continue to dissent on whether the



EML and NEML inclusion criteria of comparative cost-effectiveness should be interpreted as effectiveness per monopoly price of a new patented medicine, or as effectiveness per cost of manufacture plus a reasonable mark-up, which could be achieved with generic production within existing international legal frameworks.

Additionally, it appears that HICs may also question the relevance of NEMLs in their health care systems, as few have developed an NEML based on the WHO EML. This has been attributed to the perception that the WHO EML mainly includes drugs either related more to the LIC disease burden, or drugs that were not first-line treatment in HIC settings. Research has demonstrated that there is a lack of clarity and understanding in high income countries around the concept of essential medicines (Millar et al. 2011). It seems that HICs frequently view EMLs as irrelevant to them, as HICs already have very comprehensive procurement lists; in Australia, many key stakeholders could not distinguish between reimbursed and essential medicines, and struggled to identify how the EML concept functioned in practice, instead viewing EMLs as useful in settings with scarce resources (Duong et al. 2015).

However, the recent additions of new cancer and hepatitis C drugs to the WHO EML render it more relevant to all countries -- particularly, those countries that currently do not have a NEML such as the United States, where high drug prices of such drugs and limitations around on access are increasingly challenged.

Although the WHO EML was indeed originally devised as a tool to assist low- and middle-income countries in priority-setting in medicine selection, we are now living in a more globalized world: the global burden of disease has shifted towards non-communicable diseases (Wang et al. 2016), and

with the high cost of drugs, all countries are facing increasing challenges in delivering medications at an affordable price (Cameron et al. 2009).

All countries face resource constraints and have unique disease burden profiles that require priority healthcare needs to be set, and use of an evidence-based list of essential medicines can help to achieve this. Most importantly, the WHO EML indicates a global gold standard of medicines that should be used, regardless of location and income level. If a medicine is safe and effective, it should be considered essential to the patient who needs it, whether they live in Kibera or Sydney. We note that defining medicines as essential is just the first step toward access -- but it is crucial to secure government accountability. Accordingly, HICs will increasingly need to distinguish between EMLs and procurement lists, as costs increase.

According to WHO, a NEML should describe medicines deemed essential for the population, and serve as a guide for “procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations, and local medicine production” (WHO 2016). In line with this, YCEMP is of the view that NEMLs should describe which medicines *should* be supplied in the public sector, and national procurement and reimbursement lists should describe which medicines *are* supplied to the population.

There are a number of arguments for maintaining separate NEMLs and procurement/ reimbursement lists. First, separation of these lists could serve as an accountability system within countries, highlighting the gaps between what is considered *essential* and what is actually *available*. Second, inclusion of drugs onto NEMLs often results in price reductions and improved availability: it is important that there is an intermediate stage prior to addition to reimbursement lists through which these drugs can be identified and listed and price



reductions secured. Finally, more consistent understanding and usage of separate NEMLs and procurement lists worldwide would potentially serve to improve access through more ready comparisons between countries, and better benchmarking.

In respect of accountability, separation of NEMLs and procurement lists may, in some instances, seem unwarranted. In high-income countries like Australia, with a robust universal health coverage system, it is true that medicines on the NEML will likely be transferred directly to a procurement list. However, in countries facing significant resource constraints, there may be more of a “gap” between NEMLs and procurement lists, which countries could gradually seek to close in moving towards universal health coverage, in accordance with the principle of progressive realization recognised within the right to health in UNCESCR and in SDG 3.8. In support of accountability, YCEMP recommends that all countries maintain separate essential medicines and procurement lists concurrently, even if these are wholly duplicative in some instances.

The role of NEMLs in increasing affordability must also be noted. EMLs can be used as an advocacy tool to improve the availability and accessibility of essential medicines (Hill et al. 2012). Research across various countries has demonstrated that, when medicines are included in NEMLs, they are more frequently available than non-essential medicines (Bazargani et al. 2014) and are often more affordable than those which are not on NEMLs (Twagirumukiza et al. 2010). One reason for this is inclusion on NEMLs can prompt governments or other purchasing bodies to take action to obtain lower prices (Singh et al. 2012).

Adoption of NEMLs can also assist countries in reducing costs by helping them identify priority medicines for their health needs (WHO 2011). Prior to adoption of a NEML in the 1990s, the supply of medicines was erratic in India in spite of significant healthcare expenditure, including on medicines. Following adoption of an EML and a pooled procurement system, the government achieved cost savings of 30% in medicines, which in turn increased availability (Chaudhury et al. 2005). Other benefits are seen when NEMLs are adopted. When China implemented an ‘Essential Medicines System’, use of essential medicines approximately doubled in certain regions, partially through improved supply of these medicines (Xu et al. 2015).

For these reasons, YCEMP believes that it is important that NEMLs and reimbursement/procurement lists are not conflated. Greater clarity around the differences between these lists will enhance the conceptual value and relevance of essential medicines lists to all countries, and allow for improved benchmarking as between countries in respect of realization of access to essential medicines.

Countries should frequently monitor and evaluate the extent to which medicines included on their NEML are integrated into their national procurement and reimbursement strategies, as well as on national drug registries. This will allow governments to move toward maintaining NEMLs based primarily on clinical benefit of medicines, and thereafter take steps to realize access through public procurement and coverage.

**Recommendation 1.2: That selection of medicines onto NEMs be governed by transparent operating processes incorporating evidence-based standards, and utilising participatory processes involving diverse stakeholders.**

Presently, there is significant variation around selection processes for NEMs, which if rectified, could also see significant improvements in advancing access within countries.

At the country level, the Ministry of Health generally appoints a committee to select medicines for inclusion on the NEM, which is intended to be aligned with standard treatment guidelines. Notably, certain countries, such as India, also have state or provincial lists. When last measured, 95% of developing countries had published NEMs, and 86% of these had been updated in the past five years (WHO 2008). Nevertheless, even accounting for individual countries prioritizing their own priority healthcare needs, the fact that even the most inexpensive essential medicines such as paracetamol and oral rehydration solution are not listed on every NEM indicates that many are not up to date (Hill et al. 2012). Moreover, many of these missing medicines are universally required irrespective of disease burden, such as drugs for management of labour and obstetric complications (Hill et al. 2012). This could signal that concerns around price, availability and a host of other factors within these countries prohibit inclusion of certain medicines on their NEMs, and/or that selection processes are not functioning adequately. In any event, steps must be taken to redress these issues.

In relation to adequacy of selection processes, although a number of countries such as Kenya, India, Thailand, and South Africa now employ an evidence-based selection process (Pharasi and Miot 2013), in many countries the process and criteria for selection of medicines onto NEMs remain unclear due to a lack of transparent reporting. In other countries, there is a clear need

for an evidence-based selection process. For example, a lack of such a process in China has led to clinically inferior medicines with adverse side effects being introduced into primary care facilities (Tian et al. 2012). Cases of conflicts of interest represented within national selection committees have, for example, resulted in an imbalanced selection of medicines that do not meet the needs of the population. By way of contrast, the WHO convenes an Expert Selection Committee to meet every two years to update their EML. This process is transparent, and documented online shortly after selection has been completed. Evidence-based selection is guided by information on public health importance, standard treatment guidelines, evidence of efficacy and safety, and regulatory status of medicines.

The role of price in the selection of NEMs also varies from country to country; however, in comparison to the WHO EML, anecdotal evidence from various countries suggests that high prices of medicines frequently preclude inclusion on national lists. Again, by contrast, price was originally a major factor in the selection of medicines on the WHO EML; however, this changed in 2002, when affordability was abandoned as a precondition for selection, and was instead supposed to become a *consequence* of selection (WHO 1977; Hogerzeil 2004). This critical change was brought about by the HIV/AIDS crisis, when neither countries nor the WHO were considering clinically essential antiretroviral therapies (ARTs) as essential medicines due to their high price. Now, WHO also asks that any proposed additions to or deletions from the list, which can be submitted by any public or private entity, be accompanied by information on the drug's *comparative* cost-effectiveness within

the same therapeutic category, but no longer considers price in isolation.

In the view of YCEMP, this is reasonable. Medication prices are frequently determined by what the market will bear, as opposed to considerations for maximising access (The Economist, 2015) or national budgets, including that of households. This results in distorted markets in which any relationship to the costs of medicine production is tenuous (Henry and Searles, 2012). Accordingly, medication prices set at a level that highly-developed health systems will tolerate should not influence their selection into the WHO EML. This was reaffirmed in the 2015 WHO EML, whereby an unprecedented number of expensive and patented medicines for cancer, Hepatitis C and multidrug-resistant tuberculosis were added to the list (Science 2015).

How national lists are determined, as well as who determines these, have a great impact on people's health; accordingly, transparency is important to build public support and accountability. YCEMP calls upon countries to develop standard operating procedures inclusive of patients, prescribers, pharmacists, biomedical scientists, civil society and other relevant stakeholders, to inform selection of medications into NEMs with diversity in views and for widest acceptance. Clear responsibilities must be set for actors within each country to ensure accountability for NEM selection, updates and implementation. Additionally, these stakeholders should be free of financial or other relevant conflict of interest with the pharmaceutical industry, to avoid undue

influence and ensure that scientific evidence is central to selection decisions.

Moreover, the decision regarding whether a medicine is “essential” at the country level should be based on country need and evidence of a medications’ clinical value, including safety, efficacy and *relative* cost-effectiveness. This means that cost-effectiveness should only be considered in comparison to other medications for that particular clinical indication, and decision-making should not be undertaken in reference to prices set by manufacturers, which may subsequently be lowered through negotiation. As discussed above, a separate reimbursement or procurement list should be maintained, to which essential medicines are progressively added, based on the financial capacity of the individual country.

Finally, it is vital that countries engage the public in decision-making processes around the selection of medicines for NEMs. Involvement of citizens can lend legitimacy to internationally controversial inclusion decisions, increase public participation and engagement in a normally inaccessible, technical area of work, and promote greater advocacy for EML implementation. We propose that experts are involved in the process of selecting NEMs, but argue that these decision making processes should be embedded in broader public deliberation mechanisms such as accountability for reasonableness, based in democratic institutions to support accountability (Daniels and Sabin 2002).

**Recommendation 1.3: That all countries adopt a policy stating that, when a medicine is deemed essential, it will be made available and accessible, with concrete steps outlined that will be taken to realize access.**

YCEMP envisages NEMLS playing an additional role to those mentioned: once a country adds a medicine to its NEML, this should trigger a cascade of events resulting in the medicine being added to the national procurement list, and made available in-country at an affordable price.

From the perspective of international law, YCEMP envisages that such a system will not necessarily create obligations around immediate access to the medicine in question; rather, it will require countries to formulate a *plan* as to how access to the medicine will be realized in-country (an immediate obligation) and then take steps to progressively realize access. Such a plan should be formulated in conjunction with stakeholders, in accordance with the human rights principles of participation and transparency, and should utilize support of UN agencies or other qualified bodies, where appropriate.

Once a medicine is added to a NEML and this cascade “triggered”, there are a number of options for availability and accessibility to be secured, including but not limited to:

- ◆ Voluntary, compulsory, or government use licensing
- ◆ Importation of generics
- ◆ Sponsored entry (e.g. through Global Fund)
- ◆ Local/ Regional Production

Other steps in this process should also include acceleration of registration of procedures to minimize regulatory barriers coupled with quality assurance backed by WHO prequalification, the abolishment of data exclusivity, and availability monitoring at the country level.

One specific option that could be considered to further solidify this process is the routinization of seeking voluntary licensing or, if needed, issuing compulsory licensing once medicines are added to NEMLS. Whether this is permissible under international law is presently debated; however, there is a precedent for this process in Canada’s former routine compulsory licensing system, and other commentators have noted that there are reasonable arguments in favour of this process being interpreted as consistent with TRIPS (Flynn and Guzman 2016).

Moreover, individual countries would need to explore the legal and practical implications of implementing a system where NEML addition creates obligations to make medicines available: for instance, whether inclusion of medicines on their NEML would leave them vulnerable to litigation for failure to provide such medicines. Countries should be supported through this process by UN agencies, the WHO-WIPO-WTO trilateral cooperation or a proposed interagency task force on access to medicines (see Chapter III). Support should also be offered to countries to resist pressure preventing them from implementing TRIPS flexibilities, such as compulsory licensing (Flynn and Guzman 2016).

**Recommendation 1.4: That an *EML scorecard* be developed and implemented to improve transparency around, and monitor progress on, realization of EMLs.**

We suggest that an Essential Medicines List Scorecard be developed as an accountability tool in collaboration with relevant stakeholders (see example Scorecard, box I.IV). This EML Scorecard would serve as a tool for ensuring transparency of the development and implementation of the NEML while also promoting accountability of country-level decision-makers. Such a scorecard would also make apparent the challenges for countries in developing robust NEMLs, which would allow for the country, WHO, multilateral agencies, and other external stakeholders to target resources to improve the NEML process more strategically. Scorecards have been useful in moving countries towards improved policies in other development and health contexts as has been seen in the African Leaders Malaria Alliance Scorecard for Accountability and Action and Transparency International's Corruption Perceptions Index (ALMA 2030, 2016; Transparency International, 2016).

The Scorecard should take a human rights approach to health that might evaluate the following factors (Yamin 2008):

1. What the state is doing to fulfil their obligation to adopt appropriate measures;
  - a. Regular and evidence-based revisions to select essential medicines at the national level
  - b. Use of the NEML to ensure affordability, accessibility, acceptability and quality of medicines
  - c. Removal of regulatory barriers and implementation of mechanisms for fast-tracking of priority goods, which may involve recognition of WHO Prequalification Programme
- d. NEML and clinical guidelines are made available in all healthcare facilities and to all healthcare providers
2. How much effort the state is expending;
  - a. Efforts to lower public and out-of-pocket medicine expenditure
3. The process employed by the state toward providing universal access to essential medicines.
  - a. Clear and transparent process and criteria for NEML selection and revisions, including standard operating procedures, public participation, and public reporting of selection outcomes and justifications
  - b. A national drug policy framework supports the EML and its implementation

A biannual Scorecard would allow for public evaluation of countries on their progress to realize access to affordable essential medicines. We recommend that a proposed UN interagency task force not be involved in the development of the Scorecard (see Recommendation 2.1, below), but that an independent, external body not governed by Member States or a specific UN agency undertake administration of the Scorecard. However, the agency could be an accountability demanding institution, asking for governments and intergovernmental organisation to

Although we note that a current paucity of data on availability and accessibility of medicines restricts

the monitoring and evaluation of country progress in the areas listed above, we would hope that implementation of the Scorecard would also serve as a prompt to countries, CSOs and other agencies for such data to be collected. Increased investment in research in this area, and consolidation of national data on essential medicines and Pharmaceutical Sector Country Profiles in a WHO repository (WHO 2016), would allow for comprehensive evaluation of country progress utilizing the Availability, Accessibility, Acceptability and Quality (AAAQ) Framework (United Nations 2000), outlined within the right to health.

Box I.IV: Sample EML Scorecard	
<i>NEML Creation</i>	
<ul style="list-style-type: none"> <li>◆ Has the country created a NEML?</li> <li>◆ Has the country included or created a separate children's NEML?</li> <li>◆ Has the NEML been updated in the last two years?</li> </ul>	
<i>NEML Medicines Selection Process</i>	
<ul style="list-style-type: none"> <li>◆ Has the NEML chosen and made publicly available the criteria used to select medicines for the NEML?</li> <li>◆ Do the criteria used to select medicines for the NEML incorporate evidence of clinical effectiveness?</li> <li>◆ Is there a clear and transparent process for suggestions concerning additions and deletions of medicines on the NEML?</li> <li>◆ Are public comments on proposed NEML updates solicited and accepted?</li> <li>◆ Is there a mechanism for public health emergencies to urgently add medicines outside the usual cycle?</li> </ul>	
<i>NEML Administration</i>	
<ul style="list-style-type: none"> <li>◆ Is the NEML Committee selected via a transparent process?</li> <li>◆ Does the NEML Committee have a balanced membership of government</li> </ul>	



<p>employees, academics and civil society representatives?</p> <ul style="list-style-type: none"> <li>◆ Are stakeholders/community members included in the NEML Committee, or otherwise able to have input into its deliberations?</li> <li>◆ Are potential conflicts of interest of NEML Committee members disclosed and actively managed?</li> </ul>	
<i>NEML Assessment</i>	
<ul style="list-style-type: none"> <li>◆ Are the medicines selected for the NEML appropriately tailored to the burden of disease in the country in question?</li> <li>◆ Are the medicines selected for the NEML linked to treatment guidelines, where they exist?</li> </ul>	
<i>NEML Implementation</i>	
<ul style="list-style-type: none"> <li>◆ Is the NEML made publicly available following the selection process?</li> <li>◆ To what extent are NEML medicines available within the country?</li> <li>◆ Accessibility</li> <li>◆ Are NEML medicines physically accessible within the country?</li> <li>◆ Are NEML medicines affordable within the country?</li> <li>◆ Are any members of society currently unable to access some or all medications on the NEML due to discrimination?</li> <li>◆ Is information regarding the NEML accessible within the country?</li> <li>◆ Are medicines that are acceptable on the basis of age, sex and culture selected and made available on the NEML, within the evidence-based selection criteria?</li> <li>◆ To what extent are NEML medicines scientifically and medically appropriate, safe, and of good quality?</li> </ul>	



## II. Enabling Global Reform, Cooperation, and Consensus to Ensure Access to Essential Medicines

## II. ENABLING GLOBAL REFORM, COOPERATION, AND CONSENSUS TO ENSURE ACCESS TO ESSENTIAL MEDICINES

**Recommendation 2.1: That a United Nations interagency task force on access to medicines be created, to ensure policy coherence and improve access to medicines across all disease areas**

Concerns around innovation and access to essential medicines have been addressed to varying degrees across policy fora, typically directed towards specific disease areas such as HIV/AIDS, maternal and child health, or noncommunicable diseases (NCDs). This model could be replicated to achieve broader improvements in access to medicines.

For example, in 1996, the UN established the Joint United Nations Programme on HIV/AIDS (UNAIDS) to strengthen coordination across countries and intergovernmental agencies to address the HIV/AIDS crisis. Though its operations have not been without criticism, many would argue that UNAIDS has played a pivotal role in improving access to HIV treatment. In 2015, the target of providing 15 million people with treatment was reached - the first time in history that a treatment target has been reached by the deadline (UNAIDS 2015). In acknowledging that HIV/AIDS is a cross-cutting issue that impacts sectors outside of just health, UNAIDS took a multisectoral approach towards innovation and access to treatment.

More recently, the UN Interagency Task Force on the Prevention and Control of NCDs was formed to

similarly assemble diverse actors from across the UN system to support the realization of government commitments within the 2011 UN High-level Political Declaration on NCDs. How this taskforce will support the WHO goal to reach 80% availability of affordable essential medicines and technologies to treat NCDs in the public and private sector currently remains unclear. One of the objectives of the task force, however, is to address national capacity for R&D for the prevention and control of NCDs. Yet, concerted efforts must be made to link these efforts to broader discussions on R&D and access to medicines across various vertical disease programs and processes (WHO 2011).

Discussions around health, trade, and intellectual property with regard to access to medicines illustrate that this is not only a health problem, but entrenched in other domains. It is only through ensuring policy coherence between different processes and disease areas, with an appropriate focus on access to medicines, that improvements will be made.

## *Intellectual property and trade*

### **Recommendation 2.2: That the proposed interagency task force bring together stakeholders to reach agreement around establishing a new and more equitable system protecting and balancing innovators' and patients' rights**

Intellectual property laws, and in particular patent laws, protect the rights of innovators and allow for a person or body holding a patent over a medication to sell their medication without competition for an extended period of time. Intellectual property (IP) laws have not always applied to medications; historically, many countries considered medicines to be a public good, and therefore ineligible for patent protection (Dreyfuss 2010). However, intellectual property has increasingly been recognised as a trade issue. Patent-holders, particularly multinational pharmaceutical companies, have recognised that incorporating intellectual property protections into international trade agreements will result in protection from competition when selling products in foreign markets (MSF 2013).

The youth commission believes that this link between trade and IP has undermined access to medicines, and steps must be taken to achieve a fair balance between the rights of innovators to benefit from products they develop, and the human rights of individuals to access medications at a fair price.

Patent protections throughout the world have proliferated following creation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), an international treaty housed within the World Trade Organization (WTO) which prescribes minimum standards for IP protections for countries who have become members of the WTO. TRIPS requires that countries acceding to the WTO must make patent protection available for inventions, whether

products or processes, for at least 20 years (Article 27); this includes pharmaceutical products, and the processes used to develop them, and hereby becomes relevant for access to medicines.

TRIPS represented the first time, where IP was conceptualized as a trade issue (Dreyfuss 2010). Certain LMIC members of WTO, who opposed to the inclusion of IP in trade agreements, were ultimately won over by concessions in other areas of manufacturing as well as bilateral trade pressure from the United States (Ottersen et al. 2014), and TRIPS subsequently came into effect in 1995.

TRIPS contains some protections for public health in its text (Art. 8(1)). "Flexibilities" were built into TRIPS, primarily to allow low income countries to implement TRIPS in a way that allowed them to secure access to pharmaceutical products (WIPO 2015). One flexibility used by many countries is the extensions of time provided to comply with TRIPS. Other flexibilities, which are less frequently used, are designed to lower prices of medicines; for example, the issuance of compulsory licenses allowing for sale of medicines at a negotiated price without consent of the patent holder. In addition, the WTO ministerial declaration on the TRIPS agreement and public health (Doha Declaration) was adopted in 2001, in the wake of persistent concerns regarding the public health impact of TRIPS. It was agreed that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health...the Agreement can and should be interpreted and implemented in a manner supportive of all WTO

Members' right to protect public health and in particular, to promote access to medicines for all." (WTO 2001)

Despite developments in the use of flexibilities, the youth commission is of the view that, in totality, TRIPS has created an environment hostile to the realization of legitimate public health goals. YCEMP views that simply creating new mechanisms to promote the use of TRIPS flexibilities, or the enforcement of the Doha Declaration, will be insufficient to secure the system changes that are needed to make access to medicines genuinely equitable worldwide. Instead, a new system should be developed to replace the present TRIPS/pharmaceutical patent system that recognises the public importance of medicines, and better balances the rights of patients and consumers with those of innovators, for a number of reasons.

Firstly, given that pharmaceuticals have only recently become a key element of trade law, and indeed, have frequently been excluded from patent protection entirely in the past in certain countries, YCEMP believes that it is a misconception that pharmaceutical patent protections are inevitable, and inseparable from trade law. TRIPS is now seen as an entrenched institution from which pharmaceuticals cannot be removed, and stringent intellectual property protections for pharmaceuticals are also perceived as inarguable. This is simply untrue, and stymies discussions around implementation of a replacement system that could work more effectively for all stakeholders. TRIPS and its attendant requirements for reform of individual countries' patent protections for pharmaceuticals do not adequately balance the needs and rights of innovators and patients, and there is no sufficiently compelling historical or public policy reason why this system in its current form need remain in place.

Secondly, despite repeated attempts to redress the present imbalance between innovator and patient rights, an imbalance remains. Although TRIPS flexibilities have started to be used more in recent years, such use is still exceptional (Ottersen 2014). The Doha Declaration, too, does not appear to have provided developing countries with comfort that they would not be subject to penalties or trade sanctions for taking advantage of TRIPS flexibilities. Since 2006, use of compulsory licences has "diminished markedly", and even where countries have strong incentives to utilize them, equally strong countervailing pressures exist *not* to utilize compulsory licences (Beall and Kuhn 2012). Indeed, the Doha Declaration has been said to have "promoted only to a limited extent" the incorporation of TRIPS flexibilities into domestic law (Correa and Matthews 2011). Repeated attempts have been made by WTO and other organizations, including WHO, to encourage countries to utilize the "Paragraph 6 System", allowing for compulsory licences for certain pharmaceuticals to be issued in developing countries for production of medications for sale solely in countries with insufficient or no manufacturing capacity (Beall and Kuhn 2012); this system has only been used once. In YCEMP's view, the fact that these extraordinary, laudable efforts to improve the operation of TRIPS vis-a-vis consumers of medicines have only slightly redressed access problems, indicates that it is necessary for the present system to be entirely reexamined for change to occur at the required scale.

Thirdly, the TRIPS agreement has also been noted to have paved the way for intellectual property to become essential in trade agreements – not just those negotiated through the WTO – with the result that changes to national IP regimes are made not for health improvement, but to effectively pay for trade concessions, with the immediate effect of

preventing access to medicines (Smith et al. 2009). For countries with weak legal and economic infrastructures, the immediate benefits of increased trade “easily overshadow” the potential long-term determinants of increased IP protection on social welfare, which are also more difficult to quantify (Dinwoodie and Dreyfuss 2012). Indeed, some have even noted that there is no clear evidence that costs incurred in terms of decreased access to medicines are compensated for by “often volatile” trade advantages obtained in exchange for increases in IP protection (Smith et al. 2009).

Finally, this tilting of the balance towards increased patent protection for pharmaceuticals has raised the price of medicines in developing countries, putting the benefits of R&D out of reach for many; moreover, TRIPS “virtually assures” that diseases affecting the poor will be neglected (Dreyfuss 2010). The promised benefits of TRIPS accession for LMICs, such as technology transfer and increased innovation, have also failed to materialise (Baker and Avafia 2011). Moreover, as developing countries generally represent a small share of the world’s pharmaceutical market in terms of revenues, the marginal added value of stronger patent protection in LMICs has been estimated to be small, and unlikely to outweigh costs in terms of access (El Said and Kapczynski 2011). Least-developed countries (LDCs) in particular have faced increasing pressure to implement pharmaceutical patent and data protection. In November 2015, the WTO TRIPS Council pushed ahead with adopting a decision granting LDCs an exemption from patent and test

data protection for pharmaceutical products for the next 17 years. This decision to place a specific transition period has been met with criticism by several civil society organizations, country blocs including the European Union, and UN agencies. These critics support the LDCs’ request for a pharmaceutical transition period lasting until the country ceases to be an LDC.

For the reasons outlined above, prominent commentators have called for removal of pharmaceuticals from TRIPS altogether; in particular, the UNDP Global Commission on HIV and the Law, recommended that TRIPS (as it pertains to pharmaceuticals) be suspended, pending creation of a new, more balanced system of protection of rights (Global Commission on HIV and the Law, 2012).

An inter-agency task force could create a process bringing together all key stakeholders in the access to medicines space, with a view to securing consensus necessary to create a formal agreement (a treaty or otherwise) concerning access to medicines. It is only through a formal process involving all relevant stakeholders – including the pharmaceutical industry – that a consensus can be reached that could translate into a corresponding unanimous vote at WTO to remove pharmaceutical patent protection from TRIPS altogether. Although we note that reaching consensus on a fair system that better balances rights would be challenging, and that it is difficult to predict what such an agreement would look like, this process is both necessary and overdue.



### **Recommendation 2.3: That the trilateral cooperation mechanism between WHO, WTO and WIPO be utilized to protect essential medicines within free trade agreements**

Presently, the WTO is not the only place where IP negotiations are taking place. Through free trade agreements (FTAs) brokered externally to the WTO, governments voluntarily concede to expand IP protection in ways that restrict access to affordable medicines, in exchange for market access. With each FTA's IP provisions becoming the baseline for the next agreement, the U.S. has been largely successful in pursuing an increasingly stronger IP rights agenda for medicines (Lopert and Gleeson 2013).

Over the past two decades, the world has witnessed a surge in the number of these FTAs between two or more countries, which include the trade of health-related products (Lopert and Gleeson 2013). YCEMP anticipates that the volume of these agreements will continue to increase over the coming years. Although trade has the ability to increase a nation's prosperity, provisions within such trade agreements can pose significant threats to global public health, further undermining progress toward the Sustainable Development Goals and the achievement of equitable access to essential medicines. In particular, as HICs utilize trade agreements to export their stronger intellectual property (IP) regime to other countries, the IP provisions within these agreements impede the entry of more affordable generic or biosimilar alternatives by calling for further monopoly protection for branded small molecule and biologic medicines.

Methods used for expanding IP protection in free trade agreements include provisions that enable "evergreening", whereby minor modifications, such as new doses or delivery mechanisms, can result in new patents being granted over existing medications without any proof of increased clinical efficacy, extending monopoly protection by up to 20 years (Collier 2013). Another IP provision

commonly pursued in FTAs is requiring periods of 'data exclusivity' for biologic drugs, with terms lasting beyond the typical 20-year patent period. Data exclusivity prohibits drug companies from citing the patent holder's clinical trial data when seeking a marketing license from regulators (Reichman 2009). In practice, this would mean that if a generics manufacturer wished to receive approval for a generic version of a medicine before the expiration of data exclusivity, they would need to conduct their own clinical trials - something that would be in contravention of the Helsinki Declaration (WMA 2001). These methods of seeking expanded pharmaceutical IP protections, however, are not exclusive to FTAs.

Since the early 2000s, multinational pharmaceutical companies have sought to influence high income countries' IP agendas by serving in key advisory positions to trade ministers, while other low- and middle-income countries may have more limited technical expertise in these same areas, inhibiting their ability to create a counter agenda that would uphold TRIPS flexibilities (Lopert and Gleeson 2013). Additionally, public access to negotiating texts has become progressively more restricted, and agreements frequently contain provisions that bar release of the finalized text until years after adoption. For example, the Trans-Pacific Partnership (TPP) negotiations have been criticized for a lack of transparency. Civil society had no access to the negotiating text, while concurrently, the U.S. Trade Representative (USTR) has solicited input from industry through its Trade Advisory Committee (Love et al. 2011).

The UNDP Global Commission on HIV and the Law has considered the impact of TRIPS and the international IP regime on access to medicines in the context of HIV, and strongly condemned steps

taken by certain high-income countries to undermine the implementation of TRIPS flexibilities and impose more extensive IP protections through FTAs negotiated outside of the WTO (known as ‘TRIPS plus’ agreements). Multilateral organizations have also been concerned about the impact of the FTAs in undermining their role (Blanco 2013). In July 2013, the Trilateral Cooperation mechanism between WHO, WTO and WIPO published a report, with contributions from both civil society and industry, in response to an increasing demand “for strengthened capacity for informed policy-making in areas of intersection between health, trade, and IP, focusing on access to and innovation of medicines and other medical technologies” (WIPO, WHO and WTO 2013). The report also acknowledges the intensifying “need for cooperation and coherence at the international level”.

It has become imperative that all stakeholders come together to develop a more balanced and inclusive approach to trade agreement negotiations, specifically in regard to access to medicines. Public health advocates have suggested the creation of an independent commission to propose amendments to TRIPS, which would deliberate on legal changes that ensure the global trade regime does not restrict access to medicines (El Said and Kapczynski 2011). The recently developed multilateral body of the WTO, WHO, and World Intellectual Property Organization (WIPO) Trilateral Cooperation is one ideal forum to bring together stakeholders to develop best practices in IP rights provisions that are coherent with already established WTO rules and resolutions passed through the WHO and WIPO. The body was formed in 2008 to pool together expertise to study pricing and procurement practices of medicines and increase inter-organizational cooperation (WIPO, WHO and

WTO 2013). The trilateral cooperation mechanism, or the proposed UN interagency task force on access to medicines, could both be well placed to address the issue of “forum shifting” and convene stakeholders to draft a best practices template for IP provisions in FTAs.

The creation and adoption of model language around IP and pharmaceutical products will allow for a norm-setting process in which essential medicines are protected within these agreements. Such adoption will also prevent forum-shifting and ratcheting up of intellectual property rights by developed countries and industry creating a form of “soft law” for Member States to look to for guidance.

We acknowledge that the process will be lengthy and difficult, given the requirement of resolutions at each of the three multilateral organizations, as well as influence from powerful vested interests in developed countries. However, there is resounding support at the national and regional level from civil society and international organizations to put forth such recommendations. Such model language, however, will only have true effect if adopted by Member States through their legislative processes.

Accordingly, YCEMP recommends that best practice guidelines for intellectual property and pharmaceutical products within Free Trade Agreements should be created by the WHO/WTO/WIPO trilateral cooperation mechanism, and that countries should utilize these guidelines to draft model language, and adopt and implement legislation to realize the protection of essential medicines within Free Trade Agreements.

## **Research, Development and Commercialization**

### **Recommendation 2.4: That research and development models are implemented that incentivize innovation based on global health need and facilitate access to knowledge and goods, from basic research through to delivery of end products**

Currently, the research and development (R&D) of pharmaceuticals and other medical technologies is primarily driven by profitability rather than patient need. Paradoxically, the majority of medicines are developed for patient populations in high-income countries, whilst the majority of the global burden of disease affects people in low- and middle income countries (IHME 2013). By focusing on developing drugs for patients with the ability to pay high prices for drugs, pharmaceutical companies and their investors are ensured high returns on investment (WHO 2012; Røttingen et al. 2013). The current model for R&D incentivizes developers to recoup their investments by the price they set for the medical product. For these reasons, newly-released drugs are often priced highly, as occurred when antiretroviral drugs were first released, and as has been seen with newer cancer drugs (Abboud et al. 2013). Through the patent system, pharmaceutical developers are awarded a monopoly on drugs they develop for up to 20 years, which allow them to determine drug price without reference to competitor activity within the market.

When patients or governments cannot afford to pay for highly priced drugs, there is little incentive for pharmaceutical companies to invest in R&D to produce drugs for those markets. The lack of financial incentive for R&D based on global health needs has been widely acknowledged (WHO 2006; WHO 2008; WHO 2012; MSF 2015; KEI 2014; HAI 2012; IFPMA 2013). The poor are particularly vulnerable; for example, in relation to the lack of development of new drugs for neglected tropical diseases.

While some argue that a model wherein private companies are adequately compensated such that

R&D costs are reimbursed and sufficient profits are garnered is the only one that will incentivize necessary development of new drugs, YCEMP is concerned about the efficiency and effectiveness of the present system. Currently, monopoly rights of 20 years result in high prices for patients and health systems, with significant implications for resource allocation. Further, privatized knowledge and patented products does not necessarily result in more innovation: in fact, this can delay further developments of ideas, and skew production incentives towards low-risk propositions that add minimal value in respect of health outcomes. Of the medicines currently being developed, 85-90% have little or no added therapeutic value compared to current treatment options (Light and Lexchin 2012).

The goal of R&D should be to produce the most necessary medicines based on global disease burden, with products of such R&D made widely available at affordable prices.

To reach this goal, we recommend the following changes to reform and realign the R&D system:

#### *1. Knowledge should be considered a global public good*

We argue that knowledge – from basic scientific research through to development of end products – should be secured as global public goods, not private goods as they are in the current system. Stiglitz (1995) defines a global public good as a good that is not necessarily only both non-rivalrous and non-excludable, as per the traditional definition of Samuelson (1954), but of value worldwide. As a global public good, we envisage knowledge relating to medical R&D being made widely available, which can facilitate development of new

drugs for the public. To facilitate this, alternative mechanisms are needed. The important work by the WHO CEWG provides guidance on how this can be ensured through various approaches including: open-source collaboration and open access mechanisms; pooling of intellectual property and financing; and, global coordination through establishing of a R&D observatory (WHO 2012). These recommendations can be acted upon, and can provide incentives that can align and ensure the interests and rights of inventors, international human rights law, trade rules, and public health.

## *2. A delinked R&D system*

The costs of innovation and production should be delinked. When R&D is delinked, the end price of the product is unconnected to the development costs (Chatham House, 2015). Through *post-registration delinkage*, revenues are awarded to the developer of the medicine after successful registration of the product with a stringent regulatory authority such as the FDA or EMA, or 'prequalification' through the WHO prequalification programme. If the developer is ensured certain revenues, medicines can be produced and sold at a price close to that of production. In a delinked system, a reward is accrued for the innovative idea itself, rather than the development or production process. Hence, there can be several producers and the price no longer has to be set with the purpose of recovering R&D expenses. With monopoly rights removed, markets are opened for competition among different suppliers, which generally facilitates sale of medications at lower prices.

## *3. Global financing mechanisms should be implemented to support R&D according to global health needs*

Presently, pharmaceutical companies – and, in turn, payers – bear the burden of cost of development. However, rewarding drug developers

directly (rather than allowing them to recoup costs through legal monopoly pricing) requires alternative funding mechanisms prioritised according to global health need. We envision that, in order to support R&D as a global public good, additional financial incentives are needed. Moreover, as medicines are different from other private goods, we believe that public financing is needed.

YCEMP is of the view that, as R&D is a global challenge, countries should share the burden of costs of innovation through shared financing mechanisms: i.e. through global pooled funding. Member States should reach agreement that, through a global R&D treaty, funds can be contributed annually, e.g. at a rate of 0.01% of GDP (WHO 2012), that will be used to develop drugs that can be used worldwide .

While earlier funding mechanisms have focused on illnesses that are almost exclusively poverty-related (e.g. drugs for neglected tropical diseases) we argue that the creation of a global fund for needs-driven R&D should be broader. This is because market failures go beyond tropical diseases; greater investment in drugs to treat NCDs are necessary globally, not just in certain regions. Looking towards 2035, financing mechanisms should focus on global health need, and include R&D on all drugs, for all diseases, as the burden of disease in LMICs and HIC are overlapping (WHO 2016). This will also benefit public healthcare systems that struggle with high prices, which is of importance as countries move towards universal health coverage. Milestone prizes or other alternative financing mechanisms can be promoted by country governments and other stakeholders to speed up the process for development by offering financial reward for reaching intermediate steps in exchange for the intellectual property rights (WHO 2012).

**Recommendation 2.5: That technical assistance be provided to public research institutions to facilitate access to technologies developed in those institutions**

Public sector research institutions, such as universities and nonprofit research institutes, play a significant role in medical innovation. Such institutions have been estimated to have contributed to the discovery of as many as 21% of new drugs developed recently in the United States (Stevens et al. 2011). In the United States, the passage of Bayh-Dole Act (Public Law 96-517) allowed universities to file, own, and license the IP generated with government research funds. Many countries have since adopted similar practices (Cervantes 2016). Universities have established "technology transfer offices" (TTOs) to transfer knowledge to the marketplace, by either licensing a technology or facilitating methods for commercialization. However, there is a large diversity in the structure and organization of TTOs, both within and across countries (OECD 2003). We are concerned that licensing decisions made by TTOs may substantially undermine the sharing of research and other products developed in universities. This has implication for access to medicines because a lack of technical expertise, awareness of the diversity of licensing options, and asymmetrical power relations between researcher and licensing corporation may hinder the adoption and implementation of humanitarian licensing.

The WHO Consultative Expert Working Group on Research and Development: Finance and Coordination highlighted the role of humanitarian licensing as a way to solve the issue of high prices due to monopoly by introducing licensing strategies to ensure these products become available in LMIC either through further sublicenses with generic companies, or else by requiring the private company to ensure affordable access (WHO 2012; Chen et al. 2010). With a strong push from civil society and academia, some universities have already adopted similar policies

in their TTOs. For example, the "Global Access License Principles" of University of British Columbia (Wasan et al. 2009) encourages the licensee to ensure global access. The policy saw a success shortly after it was implemented, leading to an agreement for oral Amphotericin B, a novel agent against leishmaniasis developed by a university researcher, to be sold at lower price in developing countries. Similar examples of licensing policies or guidelines can be found in more than 16 other universities such as Yale, Harvard, Emory University, UC Berkeley, University of British Columbia, University of Oxford, University College of London, and University of Bergen (Chen et al. 2010; UAEM 2016). There is, however, less data on universities outside America and Europe, and further study is needed on the effects of these licensing policies.

Patenting university research has been shown to facilitate the transfer of technology from university to industry, but also to delay systematically the publication of research findings and hinder the dissemination of scientific knowledge (Penin 2010). There is also an increasing number and stacking of "upstream" patents for basic research results, accompanied by a high portion of exclusive licensing (Sterckx 2009; Lemley 2007) without consideration of ensuring access in the future. We are concerned that licensing decisions made by many public institutions and their researchers may not be fully informed, as a result of lack of knowledge on humanitarian licensing; moreover, at the current pace, many universities are lagging behind in terms of adopting such important practices in IP to facilitate local and global access.

We envisage that the proposed interagency task force on access to medicines could serve the following functions in this space:

1. Provision of technical support to TTOs, and sharing of best practices, for humanitarian licensing of patented discoveries and/or other licensing approaches that prioritise access to the end product globally

2. Leadership around a process establishing international norms whereby the success of research teams is not merely based on numbers of patents obtained, but rather, the accessibility and effectiveness of innovations, especially within LMICs

### ***Generics and counterfeits: consensus definitions***

#### **Recommendation 2.6: That steps are taken to adopt a consensus definition of “counterfeit medicines” and “generic medicines” as soon as practicable.**

At present, significant problems still exist due to definitional confusion around “counterfeit” medications, and those which are generic (unbranded). Until this is resolved, challenges around affordable access will persist, as efforts to improve access to generic medicines may be thwarted by equally determined efforts to limit market penetration of counterfeit drugs.

The term “counterfeit medicines” encompasses a broad selection of products, ranging from drugs that are ineffective due to an inadequate amount or total lack of active ingredients, to drugs that are actively dangerous to health: for example, due to contaminants (WHO 1992). Complicating matters somewhat, counterfeit drugs can also include drugs that are falsely labelled with branded markings, which infringe the trademark or other proprietary markings of a pharmaceutical company, but actually contain the active ingredient claimed. All of these are collectively referred to as substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medicines.

Counterfeit medicines have been described as “endemic in the global supply chain” (Mackey and Liang 2013). However, the true extent and consequences of the problem remains unknown. Few studies of good methodological quality have

been performed to ascertain the prevalence of this issue; nevertheless, the studies conducted to date indicate that poor-quality antimicrobials are widespread throughout LMICs in Africa and Asia, with the most commonly identified problem (in 93% of cases) being an inadequate amount of active ingredients (Almuzaini et al. 2013). Outside these regions, and the antimicrobial therapeutic class, there is a distinct scarcity of data in relation to counterfeit medicines.

Nevertheless, there is “broad consensus” that the criminal trade in pharmaceuticals is a serious global public health issue needing immediate attention (Mackey and Liang 2013). Indeed, the effect of counterfeiting in pharmaceutical products is now being felt in high-income countries as well (Almuzaini et al. 2013), particularly with the growth in sales of medications online.

However, one major problem in addressing counterfeiting in pharmaceutical products is the lack of an agreed international definition of *what* constitutes a counterfeit medication (Clift 2010). WHO notes that there is no universally accepted definition of “counterfeit” medications, as this description frequently extends beyond the term’s regular meaning within intellectual property (copying or imitating an original product without



authority or right, and marketing the copy as the original) and includes substandard branded products (WHOa, 2015). In the absence of consensus on this topic, the WHO's Member State Mechanism on this topic has adopted the term "substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products", which is to be used until a definition has been endorsed by the governing bodies of WHO (WHO 2015).

In addition to the present confusion around counterfeit medicines, there is also great variation in definitions and classification of generic medications worldwide. Alfonso-Cristancho *et al.* (2015) found that only two-thirds of 21 countries studied had specific requirements for generic pharmaceuticals, with only half of the countries adopting an official country-level definition of what constituted a generic medicine. There is also inadequate understanding of generics among health professionals and students. For instance, a study conducted within Boston University found that only 24% of students had an accurate understanding of what a generic medicine is (Tobin and Laing 2014).

The problem is aggravated by the tendency of some actors in the sector to discredit generics and undermine their credibility among physicians (Hassali *et al.* 2014). The attitude of physicians and pharmacists towards generics still varies worldwide, even among countries within Europe (Toverud *et al.* 2015).

This variability in perception presents a challenge with respect to promoting the use of generic drugs to minimise costs for consumers. In the absence of definitions that adequately capture the difference between these categories of medications, generics may be conflated with SSFFC medical products, stymying access.

Efforts are apparently underway to harmonize definitions of generic medications, and regulations pertaining to them—which is noted to be urgent, given the increased availability of medications whose patents have expired (Alfonso-Cristancho *et. al.* 2015). YCEMP recommends that WHO, Member States and other actors redouble their efforts to secure consensus around definitions of both generic and counterfeit medicines, and thoroughly establish the difference between these two classes of medications.



### III. Supporting Regional and Multilateral Cooperation to Achieve Accessibility, Affordability and Appropriate Use of Essential Medicines

### III. SUPPORTING REGIONAL AND MULTILATERAL COOPERATION TO ACHIEVE ACCESSIBILITY, AFFORDABILITY AND APPROPRIATE USE OF ESSENTIAL MEDICINES

#### *Health Technology Assessments*

**Recommendation 3.1: That diverse regional and multilateral health technology assessment (HTA) bodies are established that are efficient, scientifically rigorous and transparent, and take equity into account in their decision-making.**

With the release of new expensive and specialized medicines, and the inclusion of these medicines on the WHO EML, governments and medicine reimbursement agencies are facing increasing challenges in incorporating these medicines into their formularies, given the significant financial burden they represent. YCEMP believes it is imperative that national governments and other payer agencies are well equipped to take rational decisions within their local context regarding inclusion of medicines in formularies and reimbursement structures.

To inform these decisions, some countries utilize health technology assessment (HTA): a multidisciplinary process which utilizes pharmacological and pharmacoeconomic evidence to understand the additional value offered for extra money spent on a new medicine and its implications for broader health expenditure and population health (Bingefors 2003; Herndon 2007). “HTA” is a generic term but the process, its application and the subsequent medicine pricing and reimbursements vary among countries and organizations (Stephens et al. 2012).

Looking towards 2035, we expect governments and patients may increasingly avail themselves of newer health technologies on the path to universal health coverage. Use of HTA paves the foundation for universal health coverage through efficient and equitable allocation of scarce health resources (Chalkidou et al. 2010). However, while many

countries have adopted HTA processes since their first usage in Australia, and others have expressed interest in developing HTA processes, implementation can be challenging given finite resources and the level of skills required to interpret and apply the submitted evidence; not all countries have adequate institutional, policy, and legal infrastructures required for HTA, and countries may perceive HTA to be overly costly, ambitious, and unattainable (WHO and HAI 2014). Moreover, use of HTAs in the setting of a lack of adequate training may have negative effects. For instance, even some high income countries, or parts thereof – such as the public sector in the US – lack well-defined institutional HTA structures, and reimbursement agencies are rarely trained in HTA and resource-allocation decision making (Sullivan et al. 2009), which can lead to undesirable outcomes. Moreover, having evidence considered by HTAs largely generated by the private sector without external scrutiny can lead to HTAs becoming a medicine value proposition tool, with potential inclusion of medicines with limited additional clinical benefits (Herndon et al. 2007; Garcia-Altes et al. 2004).

For these reasons, it is necessary that HTA processes are rigorous, which is not always the case. For instance, Clement *et al.* (2009) analyzed retrospective records from the HTA agencies in Canada, UK and Australia and found that the use of inadequate study design, inappropriate

comparators, or invalidated surrogate (intermediate) end points led to uncertainty about medicines' clinical effectiveness. Furthermore, several agencies assess the added value of new medicines, for pricing and reimbursement purposes, by estimating the cost-savings associated with new medicine by comparing with the cost incurred in case of existing less effective or no treatment. However, as mentioned in Recommendation 1.2 on NEMs, we note the inadequacies around taking into account manufacturer-set prices in these kind of deliberations, particularly when a medicine is priced highly because no safe treatment alternative exists, and its price does not necessarily reflect its value in respect of treatment.

For these reasons, we suggest that:

*1. Countries should consider conducting HTAs at the regional and/or multilateral level*

In the view of YCEMP, there has been a lack of technology transfer between the developed and the developing world in relation to HTA programming to date, with capacity of developing countries to create and implement HTAs remaining constrained. Regional and/or multilateral HTA structures could be a viable alternative solution to creation of national HTA structures, which at present might be overly ambitious in respect of human and non-human resources.

Collaborative HTA processes not only have the potential to broaden use of HTA as an instrument for evidence-based decision making, and thereby strengthening countries commitments and ability to step towards universal health coverage (Chalkidou et al. 2010) - these could also dovetail well with other regional and multilateral collaboration efforts, such as those proposed around collaboration between national regulatory authorities (see Recommendation 3.3).

*2. HTAs should consider equity*

However, we would further suggest that any such regional and/or multilateral HTAs' deliberations be based not just on clinical and cost-effectiveness, but also on equity. Considerations around medicine coverage and pricing should extend beyond the measures of cost-effectiveness and ability to pay. HTA processes often fail to view the added benefit of a newer medicine in context to the healthcare delivery structure, disease burden and distribution of healthcare resources in a given country, which should not be the case (Chalkidou et al. 2010).

*3. HTAs should draw on the views of a variety of stakeholders*

It is important that representatives from different countries and stakeholder groups are represented on these proposed regional and multilateral HTAs. Research has demonstrated that outcomes of HTA deliberations vary significantly based on the composition of the HTA in question (Menon and Stafinski, 2011). YCEMP recommends that all HTAs should have a variety of stakeholders, including representatives from government, academia, and civil society. Moreover, citizen input should be obtained in the HTA process, in line with the human rights principles of participation, transparency and accountability. It has been noted that priority-setting for HTA is "value-laden" and efforts have been made in certain jurisdictions to increase input from more varying stakeholders, such as through citizen's juries, albeit with varying levels of success (Menon and Stafinski 2009; Menon and Stafinski 2011). HTAs have also been criticised for lacking transparency: one study revealed that over 50% of HTAs never involve stakeholders in the assessment process or final decision (Stephens et al, 2012). Given the impact of these processes on the realization of citizens' health rights, YCEMP strongly recommends that all

HTA processes (including proposed regional and/or multilateral HTAs) take steps to increase the methods through which members of the

general population can have input into these decision-making processes.

## **Regulation**

### **Recommendation 3.2: Creation and/or strengthening of regional networks of national regulatory authorities, to pool and leverage regulatory capacity for good governance, assessing and monitoring the quality, safety and efficacy of medicines and medical products.**

Regulatory and legal frameworks, including their effective implementation, are indispensable in ensuring availability, accessibility, and appropriate use of medicines. They are intended to ensure that medicines, vaccines and medical devices are manufactured, stored, distributed, dispensed, used and discarded in an appropriate and acceptable manner. However, in many countries, access to medicines has been hindered by a lack of technical capacity, in addition to unnecessary, unjustified bureaucratic regulatory processes (Narsai, Williams and Mantel-Teeuwisse 2012). This, in turn, impacts negatively upon availability of quality, safe, and efficacious medicines.

National governments are responsible for establishing strong national regulatory authorities (NRAs) with access to up-to-date evidence-based technical literature, equipment, and information, and capacity to exert effective control over pharmaceutical markets (WHO, 2012a; WHO 2013). These NRAs also ensure the availability of correct information concerning regulated products, for use by healthcare professionals and the general public. Regulation of medicines is complex, and incorporates registration, inspections, laboratory analysis, post marketing surveillance, pharmacovigilance and more (Lembit and Milan 2012). Unfortunately, in some regions, NRAs are only semi-functional, or do not exist at all - especially in LMICs (Melchior 2011), significantly hampering access to medicines for affected populations.

Some commentators have questioned whether regulation and legal frameworks are a necessary safeguard, or in actual fact, an unnecessary barrier to access to medicines (Gray 2004). It is true that, in some cases, access to medicines has been hampered by national regulatory requirements that are out of step with international standards (Narsai, Williams and Mantel-Teeuwisse, 2012). These have discouraged manufacturers/importers of medicines - that are being used in countries with functional regulatory machinery - from registering essential medicines in certain countries where they are needed. In some countries, it can take two years or more to register essential medicines for use; this unpredictability has been said to play a role in limiting market entry (Narsai, Williams and Mantel-Teeuwisse 2012).

However, this does not undermine the case for regulation *per se*, so much as it argues for improved regulatory practices to achieve a better trade-off between efficiency and safety. It is the view of YCEMP that improved regulatory practices are necessary to improve quality.

A survey of quality of antimalarials in six sub-Saharan African countries found that among 267 samples fully tested, 28.5% of them failed to comply with quality specifications (WHO, 2011a). Similarly, another study among six former Soviet Union countries found that 11.3% of anti-tuberculosis medicines were below quality specification (WHO, 2011b). More than half of all medicines are prescribed, dispensed, or sold

inappropriately, and half of all patients fail to take them correctly (WHO, 2012a; WHO, 2012b; WHO 2015). Inappropriate use has the potential to result in drug resistance in some instances, and also economic losses for countries (Ventola 2015).

Mismanagement and ineffective logistic planning have also been reported in several countries. The cause varies, from sheer lack of knowledge of supply chain management to lack of technologies (e.g. electricity for cold chain storage). Complex political contexts and policy incoherence across different levels of the government have also been suggested as the root cause of chronic medicines stockouts (ODI 2013; ODI 2014). This insufficiency in supply, coupled with the inability to monitor and regulate effectively, has fueled production and distribution of substandard and counterfeit medicines (SSFFC) in various parts of the world (WHO, 2012b).

### ***Pooled Procurement***

**Recommendation 3.3: That regional and other demand pooling mechanisms should be considered as a method to lower costs, increase access, and promote medicines supply security.**

Due to anticipated financial constraints within health system in high, middle and low income countries looking towards 2035, YCEMP believes the cost of medicines will continue to play a major role in the availability of essential medicines. Medicines are currently purchased through a variety of channels: patients, service providers (hospitals, clinics, NGOs), national ministries of health (or often provinces or districts), and international procurement mechanisms (the Global Fund or the Global Drug Facility).

The cost of medicines in a given country is primarily determined by market forces and requires state governments and pharmaceutical suppliers to come together to agree on a price. However, the medicines market has several characteristics that make price setting susceptible to failure, thereby

YCEMP believes that a lack of structured sustainable collaboration between NRAs, and duplication of efforts by regulatory bodies, contributes to these issues. Creating and strengthening regional bodies and networks of national regulatory authorities will pool and leverage regulatory capacity for good governance. Steps to improve effective implementation of core regulatory functions to support product registration and market authorization, as well as post-marketing surveillance in accordance to WHO principles and guidelines in each country, will be significantly bolstered by regional cooperation in this area. Addressing this lack of collaboration is, in the view of YCEMP, the most pressing act of regulatory reform that could secure improved access to medicines whilst refraining from compromises around delivery of quality medicines to needy populations.

increasing the prices of medications. In particular, the lack of market competition due to mono/oligopoly (one or few producers) impedes perfect competition, thereby often allowing medicine producers the ability to set higher prices.

Even for products where generic competition is permitted, the non-negotiable need for lifesaving medicines and a limited number of suppliers can lead to situations where medicines are prohibitively expensive, and in turn, withdrawal of that supplier from the market can lead to stockouts.

“Pooled procurement” denotes a centralised or collaborative method of negotiating prices with suppliers in order to bring prices down. Through pooled procurement, buyers aggregate demand to increase their negotiating power, and the resulting



efficiencies of scale and lowered risk from increased predictability of payments to suppliers result in lower overall costs. For pooled procurement to succeed, particularly in country coalitions, high levels of political commitment are necessary, as well as good quantification and forecasts of demand.

Pooled procurement has been demonstrated to lower prices at both national and international levels. In South Africa, the pooling of demand at the provincial level led to a 53% decrease in ARV expenditures, or a \$685 million savings from 2011 to 2012 (UNAIDS 2012). The Organisation of Eastern Caribbean States (OESC) and Gulf Cooperation Council (GCC) Group Purchasing Programme (GPP) both operate permanent secretariats to process tenders, and the GCC reports increased access to medicines and 37% cost savings for 25 health products over five years (World Health Organization). The Global Drug Facility (GDF) and Global Fund procurement mechanism have lowered prices and increased access for a targeted portfolio of HIV, TB, and malaria drugs (WHO 2007).

Moreover, non-financial benefits of pooled procurement have also been described. Regional pooled procurement allows for standardisation of quality and regulations between countries. Accordingly, small countries that do not have the technical capacity to assess the quality of all the medications they procure can significantly benefit from centralising their procurement through one, technically capable, agency (Mendoza 2010).

Despite relative successes in bringing down the price of some medications and ensuring overall quality, there are some unintentional consequences and limitations to current regional methods. The GDF and Global Fund procurement mechanisms only serve eligible countries, so middle income countries that “transition” out of

eligibility for these funds, especially small countries with limited demand, may encounter dramatic increases in price at a time when other external aid is withdrawn. Furthermore, there is some concern about the practices of such funds fueling market distortions; for example, Médecins Sans Frontières and other actors have criticized GAVI for accepting an unacceptably high price and supplier profit margin for the pneumococcal vaccination, in relation to which payments will ultimately have to be assumed by countries. All Global Fund grants must procure MDR-TB medicines through the Global Drug Facility (Global Fund 2012), which critics such as Keshavjee have characterized as resulting in a “moral hazard” in a “monopoly, and a situation where the people buying the medicines and the people paying for them were different”, and there furthermore is little incentive to drive down the price (Keshavjee 2012). Additionally, while pooled procurement can generate efficiencies that lower costs through bulk demand and more predictable payment, countries are primarily price takers, and suppliers may not be incentivized to bid on tenders with small mark-ups, especially when most supply lines could be repurposed to produce more profitable products. Suppliers may also be arbitrarily unwilling to participate in certain markets. As an example, while delamanid -- a critical new MDR-TB treatment -- was granted conditional stringent regulatory approval in April 2014, it is estimated that fewer than 100 patients have received the drug, and the pharmaceutical company Otsuka has not made the drug available in any low or middle income countries (Brigden 2015).

Thus, while regional procurement mechanisms can lower costs, looking towards 2035, there are severe limitations and high risk in relying on private firms that are structured to expect very high profit margins for life-saving medicines. While pooled procurement mechanisms usually seek to nurture diverse sourcing and multiple firms to encourage

competition, the possibility of suppliers dropping out or forming cartels and national laws preferring medicine purchase from local suppliers pose a serious risk to medicines availability (WHO, MSH, JSI 2007). In some situations where prices remain persistently high and capacity is available, countries or regions might consider public production of certain essential medicines as a more sustainable solution to ensuring a vital public good (see Chapter V).

Nevertheless, regional payment mechanisms can be more than a means of lowering prices on certain products--by pooling demand of states and

in turn giving private providers access to lower costs, they have the potential to shape markets and to lower final costs for both health systems and end-user costs, as patients often elect to use private pharmacies when public clinics are inaccessible or of poor quality (GAVI 2016; Sharma et al. 2016). Public and private health insurance and pharmacies may add markups to prices that still render drugs unaffordable for many despite lowered costs for suppliers, so monitoring and transparency as well as regulatory oversight of final user costs is necessary to ensure access, and for many patients and products, medicines should be provided free of charge.



## IV. Translating Essential Medicines Policies into Practice at Country Level

## IV. TRANSLATING ESSENTIAL MEDICINES POLICIES INTO PRACTICE AT THE COUNTRY LEVEL

### *Local Production*

**Recommendation 4.1:** That, in light of the potential long-term benefits of local production of medicines, robust studies are conducted in relation to establishment of local or regional production facilities.

The reliance of LMICs on imported medicines and medical technologies is high: certain countries in Africa which have the world's highest burden of HIV/AIDS infection, alongside a growing burden of NCDs, import 80% of their antiretrovirals (Sidibe et al 2014).

Recent evidence has shown that local production may improve access to medicines in rural areas (Mujinja et al. 2014). A recent UNAIDS paper discussed the potential for local production of medicines to make essential medicines more affordable, shorten supply chains, reduce the chance of stock-outs, empower local regulatory authorities, and highlighted the importance of mechanisms such as technology transfer (UNAIDS 2014).

Local production of medicines can bring benefits beyond just improving access to medicines. These benefits include technology transfer, employment and economic development. India, for example, has won a reputation as 'pharmacy of the world' for producing generic drugs, with significant benefits to its economy; although in 2005 India amended its patent law to comply with TRIPS (reserving flexibilities for medicines not classified as "innovative"), the industry continues to grow, and pharmaceuticals are now a major Indian export with the industry projected to reach USD 55 billion in size by 2020 (McKinsey, 2015). Other middle income countries including China and Brazil have also prioritised production of low-cost medicines,

increasing their market share in markets of Asia and Africa (Association of the British Pharmaceutical Industry 2014).

As accession to the WTO and implementation of TRIPS gradually imposes more restrictions on production in "pharmerging" countries, manufacturers in lower-income countries who are TRIPS-exempt for at least a further seventeen years have inherited a unique advantage. To capitalize on this, production facilities have been established in several African countries such as Kenya, Nigeria, South Africa and Tanzania, with support from the African Union, for the production of generic treatments for HIV/AIDS, tuberculosis, and malaria (AEFJN 2015).

However, the cost of production itself is typically higher for locally-produced medicines than existing equivalent generics. Local production so far has not shown to achieve demonstrable cost savings in the production of medicine (Kaplan and Laing 2005; Kaplan et al. 2011), as most active pharmaceutical ingredients must be imported from India or China, and efficiencies of scale are rarely achieved. For example, the small regional market in East Africa has meant a high cost of production for antiretroviral and antimalarial drugs by a Kampala-based firm in Uganda, with support from an Indian pharmaceutical company (Ligami 2015).

Beyond the issue of production costs, few countries have local capacity necessary to produce

much of the variety on their NEML, or to ramp up production to meet demand. The challenges include lack of local human resources or infrastructure, inadequate quality control and restrictive country policies (Hermann 2013).

Given the disadvantages countries with smaller populations and economies face in terms of their ability to afford costs associated with production, regional pooled procurement (discussed previously) or production of medications could be viable alternatives to continued external importation of essential medicines (Donga. and Mirzaa 2016). YCEMP is of the view that local production may be desirable in cases where local needs are not met by an international market (i.e. for endemic tropical diseases), and where trade restricts the importation of affordable medicines. For instance, a few high-income countries (Denmark, France and Germany) dominate the global insulin market and primarily supply insulin to other high-income countries (Kaplan et al. 2016). This leaves several lower income countries, especially those with no local insulin production,

vulnerable in terms of insulin access. In this regard, Julphar pharmaceuticals plans to establish an insulin manufacturing facility, with estimated annual production of 10 millions vials, in Ethiopia starting in early 2017. Presumably, this facility will not only meet the local need (~ 2 million vials) but the excess will be exported (Kaplan and Sharma 2015). Therefore, in emerging economies of Asia and Africa, population and industrial growth coupled with technological advancement, could facilitate local production and therefore medicines access; this can be further catalyzed by technology transfer. Growing supply insecurity further nudges LMICs to produce medicines locally. YCEMP recommends local production to be recognized as national development agenda with a long term perspective. We further recommend harmonization of policies to create supportive environment for local production where applicable. Robust studies around local production of essential medicines (including “neglected” essential medicines), monitoring the operation and relevant outcomes from local production facilities would be the first steps.

### ***Service Delivery and Essential Medicines Policies***

Much of the debate around access to medicines is focused on affordability of medicines. Although it is true that pricing is an enormous barrier to access throughout the world, there are a number of other obstacles that impede equitable realization of essential medicines access.

Often “human resource supply chains” are missing in LMICs, putting the health of individuals at risk (Brown et al. 2014). For instance, in sub-Saharan Africa, there is only one pharmacist for every 10,000 people (Soucat et al. 2013). Since pharmacies meet a significant proportion of the primary healthcare needs of the populace in countries within the region, a renewed focus on

human resources to dispense essential medications rationally is imperative. For most medicines on the WHO EML, specialised staff - nurses, pharmacists, physicians and others - are required to be trained for independent or restrictive prescribing of the treatments and to monitor the utilization of these medicines, both within and outside of the clinical settings (WHO 2015). One common example of an essential medicine that needs specialist staff for administration is morphine, 94% of which is consumed in high-income countries accounting for less than 15% of the world's population (Knaul et al. 2015). Lack of specialists and specialist training to dispense medications such as morphine, and the increasing

burden of chronic conditions worldwide, will continue to have enormous negative effects on people's quality of life and opportunity to live pain-free with dignity (Crane 2010). The fact that HICs are more prepared in terms of education and training to address the growing demand for palliative care (Cairns and Yates 2003) along with the inexcusable equity gap in access to pain relief, creates conditions that are unjust and unacceptable.

Another important issue globally is the lack of transparency about the costs of medications, both

in terms of production and the cost covered by insurers (Sharma et al. 2016). Lack of awareness about costs means that the tradeoff between generics and branded medication (in terms of cost to the system) or the end user is not necessarily considered by prescribing physicians. In this vein, Valias et al argue that cost-consciousness is an essential competency for physicians (Vailas 2012).

Accordingly, YCEMP recommends that countries revisit their policies concerning human resources for health as they pertain to access to medicines, in a number of key domains.

### ***Human resources for health***

#### **Recommendation 4.2: That healthcare service provider curricula be updated to improve workforce literacy on pharmaceutical systems, rational use and essential medicines.**

The importance of a cohesive strategy for human resources and health as a core component of essential medicines policies cannot be overemphasized, but unfortunately, there is a distinct lack of knowledge among professional healthcare providers regarding essential medicines. Regrettably, curricula for healthcare professionals in many countries – including those of medical, nursing and pharmacy schools – continue to disregard the concept of essential medicines (Mahajan et al. 2010; Mishra et al. 2016). This may have detrimental implications for the functioning of the whole pharmaceutical supply chain, starting from inclusion or selection of drugs into a NEML or procurement list, through to procurement, stock management, and rational prescribing and dispensing.

In India, where regulatory authorities failed to monitor unauthorized marketing and use of fixed-dose combination antibiotics, irrational prescribing and over-the-counter dispensing of 'prescription-only' antibiotics led to resistant antimicrobial

strains (Siddiqui and Kalara 2015). Aiming to avoid events such as these, information and structural support as well as training is needed to support adherence to recommended use of drugs.

Generic medicines are identical to a brand name drugs, and comparable in efficacy, quality and safety. They are often sold at a lower price than the branded drugs, thus present an opportunity to make drugs more affordable. However, even in developed countries, there are significant gaps in knowledge around essential medicines and, in particular, in relation to generic medicines. A study by Shrank et al. (2011), demonstrated that 23% of the surveyed physicians had a negative perception of the efficacy of generic medicines, and 50% had negative perceptions about the quality of generic medicines. In Australia, one study revealed that medical graduates and pharmacy pre-registrants incorrectly believed generics medicines are inferior in quality, less effective, and have more side effects (Hassali et al. 2007), which is echoed by findings in Iraq, where 60% of medical students



from six universities agreed that generic medicines are inferior, less effective, and produce more side effects compared to branded alternatives (Sharrad and Hassali 2011).

This limitation in knowledge is likely to have a detrimental effect on clinical practice. One study from the United Arab Emirates found only 64% of physicians adhered to the relevant essential medicines list when prescribing (Rasool et al. 2010). Another study in India found that a quarter of clinicians surveyed prescribed essential medicines, but only 15.1% of them wrote the generic names of the drugs on the actual prescription. Additionally, a third of respondent clinicians were unaware of adverse effects and contraindications of the medicines they prescribed (Mahajan et al. 2010). However, there is a dearth of evidence regarding whether this lack of knowledge of essential medicines or rational use of medicines is the reason for observed discrepancies in prescribing. This is a research agenda to pursue in the future.

There are several ways to promote the rational use of medicines. WHO has the development and use of a NEML as one of the 12 key interventions to

promote more rational use of drugs (WHO 2012). Promotion of such a list should go hand in hand with educational efforts for current and future medical professionals on rational use of medicines. Educating medical graduates on rational use of essential medicines through curricula changes can be the first step.

YCEMP recommends that professional training curricula and continuing education provided by national governments and healthcare professional associations should include concepts around essential medicines, aimed at improving service delivery and patient outcomes.

The core competencies that the entire healthcare cadre should possess in relation to essential medicines should include:

- ◆ The ability to differentiate between essential and non-essential medicines, and make rational prescribing choices with the use of treatment guidelines
- ◆ An understanding of the role of generic medicines within a sustainable healthcare system, and when generic substitution can appropriately occur
- ◆ The ability to educate and effectively communicate with patients and their families regarding the use of essential medicines

**Recommendation 4.3: That steps be taken to develop comprehensive strategies for healthcare service delivery that more effectively utilize both professional and non-professional healthcare workers, and engage patients in care.**

It is clear that adequate and well-trained human resources of health (HRH) are crucial for sustaining access to quality medicines. Improvements are needed in health systems of all countries to positively influence prescribing behaviour around essential medicines as well as manage healthcare expenditure. However, given a global shortage of about 12.9 million skilled health

professionals and the time required to train HRH (GHWA and WHO 2013), it is clear that more novel approaches must be implemented in parallel with training a sizeable professional workforce.

Task shifting and non-physician prescribing have significant potential to improve access to, as well as rational use, of medicines (Sharma et al 2013; Joshi et al. 2014). In many countries, non-

physician health professionals, especially pharmacists and nurses, are increasingly providing services like vaccinations, primary diagnostics, management of chronic diseases, and more.

Trained pharmacists and nurses have also been found to adhere more closely to standard treatment guidelines than physicians and have the potential to address rural-urban divide in access to medicines and vaccines globally (Sharma et al. 2013; Callaghan et al. 2010; Joshi et al. 2014; Sharma and Kaplan 2016; Suhaj et al. 2016). A systematic review of seven randomized control trials and 15 observational studies found that, in a majority of studies, health outcomes including blood pressure, uptake of medications, and depression scores were improved when provided by these non-physicians, compared to usual healthcare providers (Joshi et al. 2014). Task shifting has also been considered beneficial as it improves the human resource skill mix, as well as engages the community to address health needs (Zachairah et al. 2009).

Task shifting to community health workers (CHWs) has also been explored (see Box IV.1), with varying levels of success. Involvement of CHWs in healthcare service delivery has resulted in improved medication adherence and clinical outcomes (Singh and Chokshi 2013). In Haiti, CHWs helped improve HIV/AIDS treatment adherence and clinical outcomes through home visits to support direct observation of treatment and to optimize nutrition (Farmer et al. 2001). In Uganda, CHWs equipped with more treatment options as part of an integrated care program improved the rational use of medicines through

reduction of polypharmacy and prompt treatment of malaria (Kalyango et al. 2012). In Iran (Farzadfar et al. 2012) and Pakistan (Jafar et al. 2010), trained CHWs were found to be effective in the management of hypertension and diabetes. CHWs have also been utilized in TB treatment programmes, where improved adherence to Directly Observed Treatment Short Course (DOTS) was noted. This was achieved through home visits detecting symptomatic patients, facilitating sputum testing, and direct observation of patients taking medications (Perry et al. 2014).

There is also evidence of the effectiveness of CHWs in the areas of maternal and child health, and in treatment of NCDs (Mishra et al. 2015). However, there is dearth of evidence on effectiveness of CHWs in direct delivery of essential medicines. Moreover, caution needs to be taken not to overburden CHWs, nor to diminish the quality of care of the services they currently provide as they take on new tasks. There are further challenges resulting from limited training, low motivation, and inadequate supervision.

When considering and implementing task shifting, quality and patient safety must be kept in focus, irrespective of whether a setting is resource-constrained. In order to ensure that policies and programs that will improve access to medicines through alternative provider capacity-building are acceptable to the communities in which they will be implemented, patients should be included in a participatory deliberative process through which such decisions can be made, in accordance with the right to health.

#### *Box IV.I. The Community Health Worker Experience*

CHWs are a diverse category of health workers who commonly work in communities outside of established health facilities and have some type of formal, but limited, training for the tasks they are expected to perform. According to the estimates, there are five million CHWs worldwide, including 2.3 million in India alone (Perry et al. 2014). Community Health Workers are generally respected by, and are personally connected to families in their communities. They serve as an essential link between healthcare providers and institutions, and patient populations.

In considering community health workers, it must be noted that CHWs are a heterogeneous group; even within the same country there may be several types of CHWs, some who may have basic medical training, and others who do not. For example, in Nepal, there are nearly 50,000 female community health volunteers (18 days basic training with non clinical component), 2500 Maternal & Child Health Workers (basic clinical training), and 3000 Village Health Workers (basic clinical training) (Perry et al. 2014).

To realize the full potential of CHW programs, countries need to carefully consider the type of CHW that will be appropriate to the local situation and problem being tackled, and provide appropriate training, supervision, and logistical support in this context (Mishra et al. 2015; Pallas et al. 2013).

#### *HRH-EMP interplay*

Changes to essential medicines policies may have implications on functioning and behaviours of HRH, and vice-versa: for these reasons, policies must take into consideration the HRH-EMP interplay. For instance, while price control policies regulating distribution mark-ups are important, these may have unintended effects on HRH satisfaction levels, as health workers may lose a significant portion of their incomes. In Jordan, de-regulating distribution mark-ups led to price hikes, whereas enforcing mark-ups in China resulted in increased sales of high cost medicines (WHO, 2015b). Such government intervention may result in decreased motivation amongst HRH due to income losses. At the same time, engagement of both payers and providers in policy-making to improve rational use of essential medicines can lead to a positive change in prescribing behaviours (Chen et al. 2014).

Effects on medicine prescribing and utilization can also be positive (Gong et al. 2016; Zhang et al. 2015). In China, after the removal of 15% or greater mark-up of profits in prescribing and selling medicines after implementation of its new National Essential Medicine Program (NEMP) in 2009, the number of western drugs prescribed per patients decreased, as did medicine expenditure per patient; however, use of traditional Chinese medicines, and use of antibiotics remained the same (Chen et al. 2014). After the NEMP was implemented, the number of drugs per prescription decreased by 2 per 10 prescriptions, any prescription with antibiotics, corticosteroids and with two or more antibiotics decreased by 7%, 1% and 2%, respectively, with small reductions in average total expenditure (Gong et al. 2016).

For these reasons, practices and strategies for health human resource planning that are need-based, outcome-directed and that recognize the complex and dynamic nature of the factors that

impact these planning decisions need to be supported. To do so requires partnerships among stakeholders, analytical capacity, ability to access and link data with sustainable infrastructure, as well as ongoing evaluation to determine how changes in essential medicine delivery and in roles for healthcare providers influence health system outcomes.

#### *Patients as partners*

Training community health workers is only one method through which the human capital of a community can be utilized. Removal of the “strict distinction” between providers and patients can erode the unhelpful concept of patients and community members as passive recipients of medical care, and move towards improved models of care delivery where those receiving medicines are active participants in their own treatment (Bigdeli et al. 2012). This model has been employed in relation to antiretroviral treatment and child survival, and has great potential in the management of NCDs (Joshi et al. 2014; Mishra et al. 2015). There is also great potential to raise awareness of essential medicines within the general populace.

Countries and academic institutions should work to ensure the quality, relevance, and sustainability of the future health workforce (Wheeler, Fisher and Li 2014) and that personnel are trained in decision-making and management skills throughout the pharmaceutical system (Brown et al. 2014). All national governments should assess the strengths and limitations, in terms of numbers and training, of their HRH in respect of essential medicines policies, and empower both professional and non-professional healthcare staff to improve medicine access and rational prescribing. Finally, policies must be implemented to involve patients and communities more fully in healthcare and essential medicines use.

## *Transparency, monitoring and accountability*

### **Recommendation 4.4: That legislation be implemented by states mandating transparency of costs associated with the research, development, and production of pharmaceuticals, diagnostics, and vaccines.**

High drug prices are contributing to an increasing percentage of individual healthcare-related expenses, particularly in situations where out-of-pocket expenditures on healthcare are common, but also in health systems where reimbursement for medicines is undertaken collectively. The issue of high drug prices is not limited to LMICs alone, as evidenced by IMS Health reports, which note that patient exposure to cost pressures (e.g. through deductibles) is a “key factor” influencing patient adherence to prescribed medication regimes (IMS 2015). These concerns around the affordability of pharmaceuticals in all countries will become even greater as new, personalized medicines and other biologics drugs are expected to enter the market (Murugan 2015).

As national health systems move towards their commitment to implement universal healthcare coverage under the Sustainable Development Goals, they are called upon to provide financial risk protection by ensuring affordable access to healthcare goods and services, including essential medicines (WHO 2010). To achieve this, States must “expand priority services, include more people and reduce out-of-pocket payments” (Ottersen 2014). For universal health coverage to be truly realized, out-of-pocket spending for priority healthcare services and drugs must be wholly or substantially subsidized to ensure financial risk protection for citizens (Ottersen 2014; WHO 2010).

In deciding how to move towards universal health coverage, one of the tasks for countries is to choose which services to expand first (along with making choices regarding segments of the population to cover, and to what extent payment

should be covered for services selected) (Ottersen, 2014). It has been suggested that countries choose their prioritized services based on criteria related to cost-effectiveness (i.e. the effectiveness of the drug at its available *price*), concerns to those in society who are most disadvantaged, and to ensure financial risk protection (Ottersen 2014).

When considering cost-effectiveness, however, we argue that these estimates should be based on the costs of development and production of a drug, rather than manufacturer-determined prices, which frequently bear no relation to the costs of R&D and production of the medication in question (Henry and Searles 2012). Instead, policymakers’ decisions should take into account the actual cost of creation of the medication. In order to do so, R&D and production costs data must be made publicly available. If these data are not available, a knowledge asymmetry arises in favour of industry, vis-a-vis societies and countries, resulting in negative impacts on policy decision-making, and implications for patients and health systems. For these reasons, YCEMP is of the view that manufacturers should be required to report on the actual cost of R&D and production, through implementation of legislation at the national level mandating cost transparency. Accordingly, manufacturers should be required to report on the specific cost inputs of R&D of each drug that is sold on the market, through implementation of legislation at the national level mandating cost transparency.

This type of legislation has already been proposed in six states in the U.S. in 2015 and within the White House budget proposal for the Fiscal Year

2017 (Policy and Medicine 2015; Office of Management and Budget 2016). The proposals outlined in American bills are very promising and include reporting of production costs including R&D, manufacturing, and regulatory costs as well as the contributions to drug development by public institutions such as government grants. This has to be supplemented with additional cost information towards administration, marketing and advertising. Moreover, the legislation also calls for transparency of prices towards payers, including public and private insurers, pharmacies, and others. Finally, the manufacturer must also disclose the profits yielded based on these prices. All of this information is to be reported to the relevant government agency on an annual basis, with provisions to make the information publicly available and to be used to negotiate prices for those drugs found to be major contributors to health budgets.

YCEMP supports the introduction of such legislation. These legislation mechanisms should apply for all medicines approved for national use, and not only essential medicines, because it can take years to add new medicines to the WHO Model EML and/or national EMLs. The creation of a more transparent system should not be delayed. However, YCEMP recognises that there may be opposition to this proposal, given the fact that such reporting may be onerous for smaller manufacturers. Accordingly, where necessary, YCEMP recommends that cost transparency legislation be first implemented covering medications deemed essential by the country in question, before such legislation is progressively expanded to include all medications. The argument for this step could also be bolstered by monitoring and evaluation of the impact of existing cost transparency legislation; if this is proven to be a valuable tool in improving access to medicines, then its expansion will become more politically feasible.

In countries with public procurement, publication of real costs can also protect small manufacturers. In South Africa, suppliers include active pharmaceutical ingredient (API) cost information in tender bids. In the context of the volatile and depreciating rand, and the fact that most API and many finished products are imported in USD or rupee contracts, sharing information about real costs enables the government to make adjustments in prices to cover relative increases in the cost of API, which protects suppliers and is intended to aid in averting stockouts (Republic of South Africa Department of Health, 2016).

This new information regarding cost structures should, together with improved price transparency, enable policy makers and executives to use this information to negotiate better prices at the country level, as discussed in sections above. National governments would be responsible for introducing and enforcing these bills, supported by institutional and technical bodies who may be able to provide technical assistance, and also monitor and evaluate progress to ensure accountability. We note that many countries may encounter resistance in passing such legislation; however, it may not even be necessary for every country to successfully enact these laws, as we envisage that an adequate amount of utility will be gained after a certain number of threshold countries create laws promoting transparency. Civil society and media will have an important role in utilizing this data to hold governments and industry accountable.

Finally, we recommend that each country establish an independent autonomous body to critically appraise and approve the data on the costs before they are made public, allowing for increased scrutiny of the R&D and other costs reported, and compare these to the total marginal profits (the gap between marginal cost and price) from sales of the medicine. This function could be performed by bodies established to conduct HTAs, and engage in procurement, as recommended previously.



**Recommendation 4.5: That, pending reform of pharmaceutical pricing, regional price and information sharing mechanisms be established in relation to essential medicines, to enhance transparency in procurement negotiations.**

Knowledge and information concerning pharmaceutical pricing and reimbursement information can be key factors in decision-making regarding procurement of medications. In particular, benchmarking of pricing can become highly relevant when decision-makers are contemplating whether to reimburse new drugs. Accordingly, a need for increased transparency around prices paid for pharmaceuticals has been noted by various actors in the global health sphere (WHO and HAI 2008).

Presently, prices paid by governments, other payers (i.e. insurers), and consumers for medications can vary significantly between jurisdictions, even those with comparable GDPs, population sizes and other parameters (Van Dongen 2010). This is for a number of reasons, but one primary cause is the existing information asymmetry between these countries and manufacturers regarding medicine pricing. Prices set by manufacturers are frequently kept confidential, as are rebate agreements between countries and manufacturers, creating challenges for countries with limited skills who want to access comparative price information (Hinsch et al. 2014).

As previously discussed, prices are frequently determined by manufacturers based on what the market will bear (The Economist 2015), rather than by reference to cost of production or corresponding value that the drug in question represents in respect of expenditure savings. For this reason, and others, prices are open to negotiation; there can be significant room for discounts on the manufacturer-set price of medications, without eroding profits to the point where manufacturers will refuse to sell the drugs altogether. However, certain payers, particularly lower-income states or

payers therein, are frequently at a disadvantage when it comes to engaging in such negotiations because of their lack of knowledge, experience and financial power regarding the extent to which they can negotiate better prices for medicines.

Transparency and information-sharing around pricing of medications (as opposed to cost of production: see section 4.4) is one method through which the effects of this information asymmetry can be ameliorated, ideally resulting in improved negotiating power, lowered medication prices, and accrual of cost savings by governments and other payers. Improved transparency can take many forms, but the 2010 World Health Report on Health Systems Financing suggested a number of key steps to improve transparency around pricing with a view to lowering drug prices, including (WHO 2010):

- ◆ Ensuring transparency in purchasing and tenders;
- ◆ Developing active purchasing based on assessment of costs and benefits of alternatives; and
- ◆ Monitoring and publicizing medicine prices.

The WHO supports monitoring and publicizing medicine prices, which promote transparency and enable comparison for decision makers. In moving towards universal health coverage, these comparisons will become increasingly necessary, as health systems look to be able to either partly or fully reimburse more drugs. With this as a goal, countries should have an interest in sharing data, to strengthen their negotiating power.

Information sharing has particular potential in low and middle-income countries, where medicine pricing is a “critical factor” in the ability of citizens

to access treatment (Hinsch et al. 2014). However, in the view of YCEMP, information sharing and transparency in this area will become increasingly necessary globally, looking towards 2035, as healthcare budgets worldwide are squeezed by rising disease burdens and the release of many new highly-priced medications, such as sofosbuvir.

A number of regions and countries have taken steps to share information relating to pharmaceutical pricing, with varying success.

The WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (<http://whocc.goeg.at/>) is a networking and information-sharing initiative between more than 90 institutions (mainly relevant authorities and third party payers) from 45 countries. The PPRP aims to increase knowledge and exchange of information on pharmaceutical policies as well as pharmaceutical pricing and reimbursement in both outpatient and inpatient settings in EU Member States (Espin & Rovira, 2007). Price transparency within Europe is facilitated by the requirement that, while countries are free to design their own pricing and reimbursement systems, they must comply with the EU Transparency Directive (ESMA 2016). Vogler (2012) reported that, in 25 of the 29 studied European countries, through price sharing mechanisms, authorities have been able to check medicine prices in other countries to inform their decisions while setting or negotiating a price.

In the Western Pacific Region of WHO, the Price Information Exchange website (<http://www.piameds.com/>) contains information on public-sector procurement prices for selected medicines that are shared voluntarily by the participating countries. The information is collected and processed by the WHO Western Pacific Regional Office in collaboration with the University of Philippines Manila - National Telehealth Center. The Western Pacific Region established this

information exchange on medicine prices as recommended in the WHO Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005-2010).

Finally, in South Africa, the Southern African Regional Programme on Access to Medicines (SARPAM) has been supporting the Southern Africa Development Community (SADC) countries with implementation of an e-platform for sharing information on medicine prices, suppliers and medicine quality. The platform collects information from a number of countries on recent procurements, including prices, volumes, suppliers and manufacturers. This database can be used as a tool for benchmarking of procurement against other countries in the region, or as a directory for suppliers of hard-to-find medicines.

Building on these recommendations, and the recent efforts outlined above, YCEMP recommends increased information sharing between countries and/or payers, to secure more favourable medication prices and lower healthcare costs. Regional or other associated networks could be established in other parts of the world, and these could help inform medicine pricing/reimbursement decisions also in these regions, in addition to the regional functions suggested above (see Section 3.1 on HTAs).

#### *Potential challenges concerning transparency and information sharing*

Although there is significant potential for expenditure savings through improved transparency and information sharing, various commentators have noted that efforts to increase transparency may actually have a negative impact on access to medicines. In particular, it has been noted that increased transparency may cause medicine suppliers to cease providing lower prices or discounts to specific countries, or even to prompt manufacturers to withdraw their product from sale altogether in particular jurisdictions, if the

effect of information sharing is to make continued production and distribution for sale in those countries financially unviable (Hinsch et al. 2014). Moreover, price transparency could actually be most advantageous for high-income countries, because increased transparency might lead to prices converging at a lower point than what high-income countries would otherwise pay, saving them money; in contrast, low-income countries will ultimately lose out, paying significantly higher prices than they might have, were the legislation not implemented (Europe Economics, 2015). These arguments are based on the idea that suppliers currently engage in price discrimination (known as differential or tiered pricing) between markets/economies in a way that improves access to medicines.

In the view of YCEMP, these concerns are legitimate, but should not halt progress in this area, for three reasons. Firstly, despite claims about equity pricing, there are many factors other than ability to pay which affect the price paid by different groups (as determined by price sensitivity under a model of profit-maximising price discrimination by a monopolist). One of these is access to price information. Equalising access to price information among buyers would therefore align price sensitivity (and hence the price paid) more closely to each country's ability to pay. Secondly, it is perverse that a country's ability to provide access to medications may simply depend on the fact that they are in a stronger bargaining position, or have serendipitously obtained access to information that will assist them in negotiating improved prices for their populations, leaving other jurisdictions to pay more for identical medications in what becomes an effective lottery. It is alarming that basic steps taken to redress the aforementioned information asymmetry to favour access may result in

manufacturers withdrawing sales altogether, again reflecting the fundamental flaws within the present system. Finally, the human rights principles of transparency and accountability demand that these negotiations - which impact upon whether people live or die - should be, at least to some extent, in the public domain. A desire for commercial confidence is understandable, but not at the expense of human lives.

One possible way to ameliorate these concerns, to some extent, is to limit the applicability of measures concerning information sharing and transparency to medicines listed on the WHO EML, or on NEMs. In that way, commercial confidentiality can be preserved in respect of drugs that are not essential, but medicines deemed a priority and included on EMLs can be subject to improved transparency measures. Some practical challenges could arise around this: for example, where NEMs in different countries do not include the same medications. However, this could be a significant step towards improving transparency without fully removing the usage of confidential rebate agreements, for example.

In the absence of fundamental reform around pricing policies of pharmaceuticals (which YCEMP also recommends; see section 3.3) information sharing and transparency can be pursued as a next-best alternative, facilitating savings in medication expenditure. In addition to these initiatives, these networks should explore the opportunity to collaborate around procurement of pharmaceuticals (see section 4.4). Through consolidation of purchasing power, in addition to sharing of information, governments and other payers may significantly improve their position in the global marketplace, increasing their potential to favourably influence prices.

## CONCLUSIONS

For the first time since the emergence of the HIV/AIDS epidemic and the ensuing campaign for global access to antiretrovirals, there is a growing awareness worldwide of shortcomings in our current essential medicines policy frameworks. This awareness is no longer limited to LMICs alone -- restricted access to both new and existing medicines has placed the issue at the center of recent national debate across HICs. Such awareness has also prompted increasing community agitation calling for governments, multilateral bodies and other key decision-makers to act promptly and decisively to make medicines available, accessible and affordable worldwide.

We, as young professionals working in public health, will ultimately inherit responsibility for difficult decisions that need to be made when it comes to pharmaceutical policies. While we, in time, will have to make tradeoffs between clinical outcomes and designation of drugs considered essential, we envision a future in which we will not have to compromise in ensuring access to essential medicines for any patient worldwide. The power to make these vital decisions, however, presently rests with others. It is those people in positions of power that we call upon now, to make the challenging but necessary changes to essential medicines policies that will curtail preventable deaths over the next 20 years. And in making such critical changes, we call upon them to fully involve communities including patients, providers, and civil society to ensure that the policies adopted serve those affected by them.

We acknowledge the decades of work invested in EMLs - but we argue that the concept needs clarification and reinvigoration in order to ensure that these lists, the arguable birthplace of the essential medicines movement, do not fade into irrelevance. Mechanisms for transparency and

accountability at the national level to identify the gaps and challenges in developing such lists, to target resources to guide the development and implementation of such lists, and to ensure that countries are forming and using such lists with their population's needs in mind.

We recognise that not all access problems stem from intellectual property rights protection, and that changing a well-established innovator rights protection framework is daunting - but we call upon stakeholders to create this change, to better balance innovator and patient rights. This call has been echoed for years by both civil society and by previous expert and multilateral bodies including the UN HLP on Access to Medicines; growing evidence of this imbalance between innovation and access preventing patients in both LMICs and HICs from sustainably receiving treatment signals the urgency for this framework to be addressed now and in the immediate-term.

We appreciate that securing global agreement around a framework for research and development of drugs is intensely politically challenging - but we claim that it is clearly overdue, and is the only way to move forward to delink the price of medicines from the cost of their development.

We understand that limited resources prevent many countries from fully securing access to medicines at this point in time - but we note that many resource-lean options for improving rational use and reducing inefficiency exist, and call upon countries to cooperate to better leverage evidence and economies of scale to improve access,

through concepts such as regional or multilateral HTAs.

There has never been a more critical time for policymakers to address the fundamental drivers of limited access to medicines globally. As young professionals, we envision a future in which these and other recommendations are no longer confined to discussions among experts and policymakers, but made part of national and global policies and acted upon. We call upon them to stand on the right side of history, and begin to change a system that has permitted preventable deaths and suffering for too long.

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## RECOMMENDATIONS AT-A-GLANCE

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Recommendation	Action Needed	Target Decision-makers
I. Promoting Consensus and Accountability: towards a New Vision for Essential Medicine Lists	1.1: Adopt appropriate National Essential Medicines Lists (NEMLS)	Ministries of Health or national health authorities, with guidance from WHO
	1.2: Develop transparent, evidence-based and participatory processes governing inclusion of medicine on NEMLS	Ministries of Health
	1.3: Adopt a policy of outlining concrete steps to achieving access when a medicine is deemed essential	Ministries of Health, in collaboration with other ministries
	1.4: Develop EML scorecard to monitor state progress on NEMLS	WHO or other UN level body and Member States
II. Enabling Global Reform, Cooperation, and Consensus to Ensure Access to Essential Medicines	2.1: Establish UN interagency task force on access to medicines	UN Secretary-General, UN General Assembly
	2.2: Establish more equitable system balancing innovators' and patients' rights	Governments through national legislation
	2.3: Protect essential medicines within free trade agreements	WHO, WTO and WIPO
	2.4: Incentivize R&D based on global health needs and knowledge as a global public good	Resource pooling in funding through governments and WHO (through an R&D treaty)
	2.5: Provide assistance to public research institutions in disseminating their technologies	Universities, governments, cross-country or international technical agencies
	2.6: Adopt consensus definition of counterfeit and generic medicines	WHO and its member states

## RECOMMENDATIONS AT-A-GLANCE (Continued)

Recommendation	Action Needed	Target Decision-makers
III. Supporting Regional and Multilateral Cooperation to Achieve Accessibility, Affordability and Appropriate Use of Essential Medicines	3.1: Establish rigorous, transparent, equity-focused regional and cross-country HTA bodies	National, regional and multilateral cooperation through global standards; WHO may facilitate
	3.2: Strengthen regional and multilateral networks of national regulatory authorities	WHO to facilitate cooperation information sharing on global standards
	3.3: Establish demand pooling mechanisms lower costs, increase access, and promote medicines supply security	WHO to facilitate cooperation information sharing on global standards
IV. Translating Essential Medicines Policies into Practice at the Country Level	4.1: Conduct studies on the potential benefits of local or regional medicines production	Academic institutions and independent non-governmental organizations, in collaboration with local manufacturers
	4.2: Improve workforce literacy on pharmaceutical systems and rational use of medicines through curricula updates	Ministries of Health and Education; implementation strategies by health providers
	4.3: Develop healthcare service delivery strategies to utilize the skills of professional healthcare workers, non-professional healthcare workers and patients	Government, academic and healthcare institutions
	4.4: Legislate mandating transparency of costs around research, development, and production of essential medicines	National governments
	4.5: Establish price and information sharing mechanisms	National governments, technical agencies in international or cross-country collaboration

Civil Society has an integral role to play across all of our recommendations in mobilizing advocacy and accountability of stakeholders.



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