BRIEFING PAPER

PAYING FOR MEDICINES UNDER UNIVERSAL HEALTH COVERAGE

SUMMARY

Universal health coverage (UHC) is defined as all people in a country being able to use the quality health services they need without being forced into poverty. It is grounded in the human right to health. Paying direct cash when consulting a health professional or receiving a service is increasingly accepted as unfair because it deters the poor from accessing services and endangers vulnerable communities financially. The impact of paying cash when medicines are needed, however, has had less consideration.

In most low- and middle-income countries, medicines often make up the majority of out-of-pocket spending on health. Out-of-pocket spending on medicines increases inequality and results in poorer health outcomes because people either forego medicines altogether or purchase incomplete or substandard therapies. The absence of government-led systems of UHC that include medicines also results in significant inefficiencies as purchasing pools are more fragmented, generics are less frequently purchased and there is greater potential for the purchase of spurious and falsified drugs. Inappropriate and unsafe use of medicines, leading to problems such as anti-microbial resistance, may be another result if medicines are not included in adequately regulated public health systems.

In order to prevent these problems, Save the Children argues that essential medicines and health commodities should be free at the point of use under the principles of UHC within well-regulated public health systems. This means that countries must shift the burden of medicines costs from the individual to the collective by raising more money for health services and medicines, financing this through progressive mandatory prepayments such as tax, pooling the collected resources and effectively allocating them through strategic purchasing. Allocations should be based on public health needs and human rights obligations, focusing on the most vulnerable and marginalised populations.

Governments must make use of all of the tools available to ensure efficient purchase of low cost, quality medicines. These tools include increased use of generics, robust competition, pooled procurement and use of TRIPS flexibilities. Other countries and key stakeholders must not undermine their right use these tools. Countries will also need to take into consideration the resources available in order to progressively increase the scope of medicines coverage within and as a part of health coverage as a whole. As a starting point, Save the Children believes that all medicines on the WHO Model Essential Medicines List and those necessary for the Reproductive Maternal, Newborn and Child Health (RMNCH) continuum of care should urgently be made available. As well as procurement and purchasing, governments should regulate and enforce existing regulations medicines to reduce the risk of inappropriate use.

Save the Children calls on governments to commit to progressively include medicines under systems of UHC and to make all RMNCH and essential medicines available free at the point of use urgently. Governments should also ensure the most efficient purchase of medicines to make the most of their

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money, such as through use of the tools discussed above. We also call on the pharmaceutical industry to improve its tiered pricing schemes in order to better take into account national capacity to purchase, the impact of increasing coverage, in-country equity and other public health-related considerations.

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Introduction

Universal health coverage (UHC) is defined as all people in a country being able to use the health services they need without being forced into poverty, that those services are of sufficient quality to be effective.[1] UHC is grounded in the human right to health, which is recognised in nearly all major international human rights treaties.

In recent years, UHC has gained a lot of attention, with the World Health Organization (WHO) and the World Bank making it their top priority; it is likely to be included in the Sustainable Development Goals. The Director of the WHO, Margaret Chan, has said, "I regard universal health coverage as the single most powerful concept that public health has to offer. It is inclusive. It unifies services and delivers them in a comprehensive and integrated way, based on primary health care."

Debates around UHC regularly discuss access to and payment for health *services* – diagnosis, advice, treatment and care from a health professional. However, medicines and other health products are not always mentioned.

Thus, while discussions have emphasised the harmful impact of user fees and other similar payments at the point of use in deterring the poor from using services, far less attention has been paid to the equally harmful impact of cash payments on access to medicines and other health products on health outcomes. It is crucial that access to medicines becomes more central to debates about how to work towards UHC, while recognising that paying for medicines must be a part of paying for the health system as a whole.

In most low- and middle-income countries (LMICs), the majority of the money that households spend 'out of pocket' on health is for medicines. Medicines and other health products are not generally included free at the point of use in health systems around the world. As with charging for services at the point of use, when poor people have to pay for medicines out of their own pockets a number of damaging scenarios ensue: some feel compelled to cope without the medicines; other people scrape together the money to pay for medicines but are pushed deeper into poverty as a result; other people purchase incomplete courses of treatment or cheap – and potentially substandard – products.

Charging for medicines at the point of use also has a damaging impact on health systems and public health. For example, health systems are denied the opportunity to reduce costs through bulk purchasing or to ensure broad use of generic equivalents to branded products. Inappropriate use of medicines leads to wastage, poorer public health and growing drug resistance.

Along with the focus on access to and payment for health *services*, equal priority must therefore be given to ensuring that good quality medicines and other health products are available free at the point of use in public health systems. This is vital to achieving UHC.

While many different health system factors influence access to medicines (as briefly discussed at the end of the paper), this paper focuses on how public health systems and governments can pay for

essential medicines and health products and ensure that these are available and affordable for all. It argues that essential medicines and health technologies should be financed in the same way that we recommend for health services: through mandatory and fair pre-payment into government-led systems, and through pooling and equitably allocating this funding to ensure that the most essential medicines and products are provided based on need, not ability to pay, and free at the point of use.

Human rights and essential medicines

Numerous international agreements and treaties recognise the right to health for all – including the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights (ICESCR), the Convention on the Rights of the Child and the WHO Constitution. The right to health can also be found in many national constitutions, either explicitly or implied, including the South African Constitution, the Guatemalan Constitution and as part of the right to life in the Indian Constitution.

Access to essential medicines and vaccines is a minimum core component of the right to health as articulated in Article 12 of the ICESCR.[2] Currently, 163 countries are party to this agreement, which means that each of those countries is legally obligated to ensure that the right to health, including access to medicines and vaccines, is realised.[3]

In particular, this means[4]:

- As a minimum, governments must ensure that essential medicines and health technologies are available, accessible, acceptable and of good quality.
- Governments must make sure that these medicines and vaccines are available and accessible without discrimination, based on any status, focusing first on meeting the needs of the most vulnerable and marginalised groups.
- Where resources are limited, the international community has a responsibility to provide support to ensure that the minimum requirements of the right to health are met.
- Other countries and key stakeholders, including private companies, must also refrain from actions that interfere with another government's ability to progressively realise the right, such as through expanding intellectual property protections in free trade or similar agreements.

The concept of progressive realisation and what that means in terms of government obligations will be discussed later on in this paper.

Inequality, inefficiency and inappropriate use

Out-of-pocket payments increase inequalities

The 2010 World Health Report states that, "Systems requiring direct payments at the time people need care – including user fees and payments for medicines – prevent millions from accessing services and result in financial hardship, even impoverishment, for millions more."[5]

Yet today, in many LMICs, a significant number of people still pay for much of their healthcare out of their own pocket at the point of use. There are a variety of reasons for this – among other things, a lack of immediately available free, good quality public services, a preference for or forced reliance on private providers, or a lack of risk-pooling.

Paying out of pocket at the point of use has a disproportionately negative impact on the poorest and most vulnerable people because a greater percentage of their household income will go towards the payment for a health product.[6] When poor people are required to pay for medicines out of their own pockets, they may:

- choose to buy the medicine and be driven further into poverty.
- choose to go without the medicine, with potentially damaging consequences for their health and their livelihood. As the President of the World Bank, Jim Kim, has said, "Anyone who has provided health care to poor people knows that even tiny out-of-pocket charges can drastically reduce their use of needed services. This is both unjust and unnecessary."[7]
- choose to buy partial doses of medicines, such as antibiotics, where the full course is too expensive or to share a course with more than one person.
- buy sub-optimal – and even fake – medicines.

All these scenarios exacerbate financial and health-related inequalities and are examples of the injustice that results from the inability to pay.

While average out-of-pocket spending (OOPS) on medicines in LMICs is around 30%, in poorer households it may account for the majority – up to two-thirds – of all health expenditures.[8] For example, in India OOPS on medicines is about 80%, and amongst the poorest 20% of households nearly 80–90% of health expenditure is on medicines.[9] If out-of-pocket payments for medicines make up the majority of all household health expenditures for the poorest households in many cases, then price of medicines and other health products will play a major role in limiting access to healthcare and potential further impoverishment of the poorest and most marginalised.

Making essential medicines and health commodities free at the point of use, financed through progressive mandatory prepayment, is the best way of shifting the financial burden of healthcare from the individual patient to the population. It is therefore essential to building an equitable health system.

Why vaccines are provided for free and most medicines are not

National immunisation programmes give a vision of how medicines might be provided through public systems in an adequate, equitable and sustainable manner. Coordinated global and national efforts have been successful in improving coverage of national immunisation systems and helping to reduce child mortality. Coverage rates are getting close to universal in many low-income countries.[10] Some of this has been financed through international support, such as through Gavi, to low-income countries, with the remaining costs of immunisation being borne by governments themselves. In contrast, with the exception of some support for medicines such as antiretrovirals for HIV, there has been less focused international support for the provision of medicines in LMICs.

Unlike medicines, the case of vaccines demonstrates that governments can systematically take the action needed to ensure near-universal coverage of a health product. Vaccines are almost always provided free at the point of use by governments with no suggestion that populations ought to pay to obtain them. It is therefore important to ask what distinguishes vaccines from medicines?

First, in contrast with medicines, vaccines address a limited set of medical conditions. Second, vaccines are preventative and reduce the transmission of infectious conditions, and as a result are prioritised as very cost-effective public health interventions. Third, vaccines are administered almost universally to children within a discrete and easily schedulable period of time – which allows governments to forecast annual vaccination needs. Finally, vaccines are extremely donor-friendly because they are cost-effective and have long-term outcomes that can be relatively easily measured.

While ensuring adequate, equitable, sustainable access to vaccines may be easier than for medicines, it does not mean that ensuring access to essential medicines ceases to be a human rights obligation or that it is unachievable. Many steps must be taken but an important first lesson is the experience of vaccines. If there is appropriate political commitment to coverage and there are sufficient and clearly allocated resources, governments can provide medical products free at the point of use even in complex and difficult situations on the ground. The question, then, is whether sufficient political will exists to do the same with medicines as has been – and continues to be –achieved with vaccines.

Paying for medicines out of pocket results in inefficient in health systems

WHO estimates that, "Medicines account for 20–30% of global health spending, slightly more in low- and middle-income countries […]".[11]This cover both public spending, which is relatively low in most LMICs, and private spending – which is relatively high in those same countries, as discussed above. Much of this money is spent inefficiently and inappropriately.

The 2010 World Health Report identified the ten leading causes of health system inefficiency.[12] Of the ten, three had to do with medicines and other health products, including underuse of generics, use of substandard medicines, and inappropriate and ineffective use.[13] As countries progress towards UHC, there is an even greater need to address such inefficiencies in order to ensure that the demand for the right package of health goods and services can be met through public financing.

- Underuse of generic medicines

Using the lowest priced generic medicines over more expensive branded medicines significantly reduces costs of medicines.[14] This is true both for households buying directly out of their pockets and for governments purchasing for their populations. Yet in many countries, particularly LMICs, the use of generics is relatively low.[15] While private sales to individuals may be fragmented and uncoordinated, through bulk public procurement and distribution, governments should be able to ensure consistent purchase of best priced, quality generic medicines. As public health systems take on more responsibility for the purchase of medicines and health products, it will become increasingly important that these products are secured at the lowest possible prices, which will mean promoting generic competition and maximising generic procurement. Many international procurers, such as PEPFAR (The US President's Emergency Plan for AIDS relief) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), are already taking this route.

- Spurious or falsified medicines

In improving health system efficiency, governments must also make sure that the lowest cost medicine is also of good quality. While accurate data about the quality of medicines is notoriously hard to come by, it is highly likely that some of the medicines in circulation in LMICs are spurious or falsified.[16]

Similar to inappropriate and irrational use of medicines, discussed in the next section of this paper, inclusion of medicines in a well-regulated public system can better tackle the problem of spurious and falsified medicines. Robust and practical quality management systems that can control the quality of medicines available on the national market – through strict importation checks, tight regulation of national manufacturers, oversight of distributors and the standard of storage premises – are critical in this regard. Implementing these controls will require countries to develop technical competence, for example, in the role of auditors, as part of a broader inspectorate. Enforcement of regulatory systems more generally is equally important.

Lack of regulation drives the inappropriate use of medicines

In many countries, appropriate policies are not in place to adequately regulate or monitor prescription practices. Furthermore, in private sales, there may be an incentive to prescribe or sell medicines where they are not needed or used inappropriately.[17] Inappropriate use of medicines worsens the growing and already serious problem of drug resistance, particularly for antibiotics and other essential treatments, which itself has both health and financial implications.

Some inappropriate use of medicines could be addressed through improved and increased inclusion of medicines in adequately regulated public health systems.

- Anti-microbial resistance

Anti-microbial resistance (AMR) is a serious and growing concern. It has been estimated that, by 2050, AMR could be responsible for 50 million deaths annually.[18]

The reasons behind this phenomenon are complex, including inappropriate and unregulated use of antibiotics in farming, but it is also driven by the absence of appropriate regulation and supply.[19] Nearly two-thirds of all antibiotics are sold without prescription through unregulated private markets.[20] As identified earlier, this may lead to buying inappropriate antibiotics, half courses or sharing courses.[21]

Increased resistance leads to the need for second- and third-line treatments that are usually much more expensive, putting an additional strain on health systems. For example, while first-line HIV treatment is about $100 per year, third-line treatment is over $2,000.[22] The same is true for tuberculosis (TB), where first line treatments are relatively inexpensive, but second- and third-line treatments cost much more.[23] The overuse of antibiotics to treat acute respiratory tract infections in low- and middle-income countries is estimated to add an average 36% to the cost of care.[24] The modification of standard malaria therapy due to AMR, from chloroquine (CQ) and sulfadoxine/pyrimethamine (SP) to artemisinin-containing therapy (ACT), makes the cost of malaria treatment ten or more times more expensive.[25] Furthermore, AMR leads to substantial healthcare utilisation, as infected patients require longer hospital stays and more treatment. This situation is exacerbated for children. Evidence from the USA showed that for patients under 18, AMR was responsible for 39% of pneumococcal pneumonia costs.[26]

Children in LMICs are at particular risk. Evidence shows that the reported rates of neonatal infections are up to 20 times higher in LMICs than in high-income countries.[27] Similarly, the increase in AMR is more likely to affect countries that have high malaria, HIV or TB rates.[28] Dysfunctions range from using sub-standard and counterfeit drugs, to supplying drugs at a sub-optimal therapeutic level.[29]

As AMR develops faster than the rate of new medicines discovery[30], pharmaceutical companies and governments must invest more in the research and development of new forms of antibiotics. But solutions are also needed at the health system level: integrating antibiotic regulation into health systems to enhance quality, stewardship and surveillance. [31]

Paying for medicines within universal health coverage

In order to make access to medicines more equitable, reduce inefficiencies and curtail inappropriate and irrational use, medicines must be included in and better integrated into public health systems. This shift, however, has implications for government responsibilities and budgets.

Moving from out-of-pocket expenditure to public financing

As has been demonstrated for health services, the fairest and most efficient way to ensure access to medicines and other health products is for governments to ensure mandatory and fair resource pooling.[32]

There are currently schemes such as revolving drug funds, in which an initial sum of money contributed by the government or other stakeholders is used to purchase a stock of medicines that are then sold, and community based health insurance schemes (CBHIs), which may be used to facilitate the purchase of medicines. While these may demonstrate some success, they are difficult to implement, and examples of successful large-scale programmes are limited, meaning they operate on too small a scale to have sufficient impact. As voluntary mechanisms, they cannot sufficiently cross-subsidise from the 'healthy and wealthy' to people who are sick and poor because there is no reason for the former to enrol voluntarily. In revolving drug funds, the individual or the household often still bears a financial burden through some payment at the point of use.[33] Research also shows that financing through CBHIs is limited, because adverse selection tends to result in a low level of revenue pooling[34,35] and they often exclude certain groups.[36]

Large-scale, mandatory prepayment schemes – with contributions based on the ability to pay and access based on need – must be the model.[37,38,39]

Shifting from private to public expenditure will poses problems for LMICs where health systems are already severely under-resourced. This challenges governments to mobilise increased resources for health. As more new medicines are developed – new treatments, adapted treatments or second-line

drugs to deal with resistance – the bill for essential medicines will get more costly. How countries approach this demand is discussed below. It should be noted that poorer countries already spend proportionally more of their health budget on medicines than the wealthier countries.[40]

The impact of adding new vaccines to national immunisation packages and what it suggests for medicines

Vaccines serve not only as an example of how medicines can be successfully included in public health systems, they also point to the problems that countries may face as they increase the number of medicines available within the public systems of UHC.

Even for vaccines, which are considered to be the most cost-effective health intervention, the total cost of including all of the WHO's recommended routine bundle of vaccines puts great fiscal pressure on countries. As Médecins Sans Frontières (MSF) has pointed out, the total cost of this bundle has increased from a little over a $1 in 2001 to over $40 today for Gavi-eligible countries; prices in other countries are substantially higher.[41] While part of the reason for jump in cost is because the recommended bundle of vaccines has expanded to cover nearly double the number of diseases as it did a decade ago, the cost of the total bundle has at a much faster rate to 68 times the original amount.[42]

There are already signs that middle-income countries (MICs) may not be able to sustain the introduction of new vaccines. In some cases, MICs have been unable to introduce vaccines that have already been introduced in poorer Gavi-eligible countries as they are unable to access to sufficiently low prices.[43] Some countries such as Tunisia, Lebanon and Morocco are actually paying more per dose for the pneumococcal vaccine than wealthier countries such as France or the Czech Republic.[44] Irrational pricing such as this inhibits countries' abilities to meet their human rights obligations and of course has a highly detrimental impact on the health and well-being of children.

Ending all preventable child deaths will require the availability of and accessibility to many additional medicines, including newer and more costly ones. Governments will have to find ways to increase the amount of resource they put into health and, equally importantly, ways to ensure that they are getting the lowest possible price for all the medicines, vaccines and health technologies that they need to include in their health system to ensure that children's right to health is realised.

Progressive realisation and priority setting

As discussed above, no government, not even the wealthiest, can make all possible medicines and vaccines available. UHC discussions set out the considerations of how much of the population is covered, which services are within the package and what kind of co-payment can be expected. Save the Children supports the concept of 'progressive universalism' proposed by the Lancet Commission on Investing in Health: that governments should aim to cover the whole population as quickly as possible in any UHC scheme and with minimal or no cash payments expected at the time of use. However, the package of services should start with the most essential, based on population health needs, and expand as resources become available. This means that governments must be mindful of human rights and public health obligations as they progressively expand the scope of medicines covered and ensure that the most vulnerable and marginalised groups are the first focused upon.

What is progressive realisation?

Progressive realisation is the acknowledgement of the impact of resource constraints on the realisation of economic, social and cultural rights.[45] It allows countries to take into account the resources at their disposal in realising the rights of the individuals who live in those countries. What this means is that countries must make maximum use of their available resources, and actively increase the amount they spend on health and where necessary to recruit international support, in order to build health systems that prioritise the needs of the most vulnerable and marginalised groups. What it does not mean is that

resource constraints may be used to justify a lack of progress or retrogression in the realisation of any right.[46] Further, regardless of resourcing, countries must still meet a minimum core set of obligations (many of which do not require significant public outlays), including non-discrimination in the availability and accessibility of public services and providing essential medicines.[47] This must include not only measures to reduce and contain medicines costs, but also to build up all of the other health system components, such as procurement, regulatory, and pharmacovigilance systems, that support availability and accessibility of medicines.

It also means that governments must simultaneously take all necessary steps – such as pooled and bilk procurement, regulation, using TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) flexibilities, price controls, and compulsory licenses – to increase the availability and accessibility of good quality medicines for the poorest. Many such steps can be taken immediately because they do not necessarily come with corresponding costs and would alleviate potentially discriminatory inequalities. Although many of the most vital, yet unavailable medicines are already available in inexpensive, quality generic versions, others, such as hepatitis C or cancer medicines, remain very expensive and therefore inaccessible.

Save the Children believes that the obligation to progressively realise means that governments must first prioritise the reproductive, maternal, newborn and children's health (RMNCH) continuum of care as the basis of UHC. Ensuring the best health outcomes for women and children through strong primary care services is the strongest and most equitable foundation of a health system that is aligned with human rights priorities. Gender equality considerations may mean prioritising those medicines that have a major impact on the health of women and children – such as those found on the WHO Model Essential Medicines List and others that impact the RMNCH continuum of care – must be included within the scope of coverage at a minimum.

- Medicines currently not provided in government systems

Recognising that all essential medicines should be available through systems of UHC, there are two categories of medicines that are unlikely to be immediately prioritised. The first are non-essential medicines for non-debilitating conditions such as relief of low-level pain, cold symptoms and similar conditions that have no major long-term health implications. As resources allow, these might also be available through public systems to reduce inequality of access but are unlikely to be a priority because they are also generally available at low cost through private markets.

The second category comprises those expensive medicines that are for more serious conditions not currently covered by the public health system due to resource constraints. These medicines should, however, be included in the future when sufficient resources become available. Governments in such cases must recognise that poor and marginalised families and individuals may purchase these medicines directly. Therefore, as an interim measure, governments should endeavour to ensure as a minimum that out-of-pocket costs resulting from the purchase of these medicines and health technologies are reduced and more equitable. As Save the Children has previously stated, private suppliers should employ pricing policies that take into account, among other things, intra-country inequity such the different costs that different communities can bear.[48]

- Tools countries should use to lower prices of new medicines

As discussed Save the Children's briefing paper on tiered pricing, countries need to use all available tools to ensure that medicines and other health technologies are available to them at the lowest possible and sustainable prices. [49] This is particularly true for patented new medicines which are generally more expensive. These tools include:

- Bulk purchasing, through accurate forecasting for long-term contracts at reduced rates, and pooled procurement, through which countries may leverage better prices.
- Use of TRIPS flexibilities to increase generic competition and drive down prices for new medicines.

- Voluntary licensing and patent pooling
- Other pricing policies and solutions such as mark-up restrictions, price control and mechanisms for technology transfer to generic companies.

The global community and key stakeholders must support countries to take these actions and these decisions should be guided primarily by health needs and human rights obligations.

What is also clear is that by taking control of medicines under systems of UHC, countries can negotiate better prices and ensure availability in a fairer way than if left to the private market and out-of-pocket payments. However, as countries increasingly become the primary procurers of medicines, without broader price information they will be at a serious disadvantage in price negotiations. The 2010 World Health Report states, "Without such cross-country price information, buyers can struggle to obtain a fair deal in a global pharmaceuticals market that is neither transparent nor efficient, and where there is an enormous range in the prices paid for identical products." Although many factors affect a country's negotiating power, including the size of its market, transparent pricing information will help countries procure at better prices. Both countries and companies should strive to make public as much price-related information as possible.

- Health technology assessments

An increasingly popular way of rationally deciding on which medicines should be provided through national health systems is though a health technology assessment (HTA). An HTA "refers to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology".[50] It is a means by which countries can set priorities for the progressive realisation of the right to health and move towards UHC. HTAs allow countries to take into account a broad range of factors – cost-effectiveness, and social and ethical considerations – in determining whether to include a particular medicine or health technology with the scope of coverage.

HTAs have maximum value when they are done properly and are tailored to the health system concerned. Although such assessment mechanisms are often resource intensive, they are not out-of-reach for LMICs. HTAs go beyond value for money assessments and may help governments to appropriately balance social and economic considerations. There are also means through which the human resource and knowledge gap can be bridged, including developing regional mechanisms, which pool capacity. If efficiently led, HTAs can result in the strengthening of the legitimacy for policy decisions, as well as an increase in transparency, inclusiveness and accountability in the decision-making process.[51]

Prior to the technology assessment *per se*, health topics are selected according to their priority level. As HTAs differ from country to country – according to national contexts, including existing political structures and cultural values – criteria for assessment vary widely. Brazil takes into account the epidemiological relevance of the intervention and its quality for the patients, but also considers opportunities for the national market as well as the potential budgetary impact of the decision. In Colombia, however, despite the legal inclusion of diverse criteria, it is still often solely the cost of technology to the system that mainly drives decisions. In some countries, criteria are not formally defined, as in Poland. [52]

HTA in Thailand and Latin America: Potential ways forward?

One example of HTAs worth investigating is Thailand. The HTA process is led by the Health Intervention and Technology Assessment Programme (HITAP), a semi-autonomous body reporting to the Ministry of Health. The HITAP informs upon which medicines should be included in the national benefit package – it does not asses all pharmaceuticals in a systematic way but those for which a request has been submitted by external stakeholders.[53]

Thailand's HTA success is based on a large participatory and transparent approach. Research has

shown that not only were policy-makers, citizens and the healthcare industry allowed to participate, but they effectively grabbed this opportunity to speak up.[54] Finally, HTA also allows for price negotiations with pharmaceutical companies.[55]

Thailand's HTA does not only rely on cost-effectiveness and budget impact for determining whether a medicine should be included or not.[56] The selection of priority topics includes a number of criteria: the magnitude of the problems (the number of people affected and severity of the condition), the effectiveness of the existing interventions, the variation in practice and the financial impact of the topic for the households, and, crucially, equity and ethical dimensions. Particular attention is given to the problems of marginalised populations as well as rare conditions.[57] Thanks to this diversity of criteria, Thailand has been very successful in progressively expanding the scope of coverage of its national health system in a largely equitable manner.

However, HTAs processes are rarely formally designed and do not always lead to informed resource allocation decisions.[58] In Uruguay, for example, there is no formal process, and health technology assessment is often limited to an economic evaluation supporting the coverage decisions for high-cost medicines.[59] Nevertheless, many countries are moving towards a systematic prioritisation process for the selection of relevant topics. A promising initiative has been initiated in Chile, where a National Health Technology Assessment Council was created in the Ministry of Health in 2012. By gathering 16 members of the Regulatory Authority guiding the work of two technical advisers, it aims to formalise and develop a systematic approach to HTA, based on normative criteria as well as international experiences and according to the country's capacities.[60]

A different but just as noteworthy mechanism guides the commercialisation of pharmaceuticals in Brazil. Prior to inclusion in the SUS benefit package decisions, the Brazilian Health Surveillance Agency (ANVISA) issues marketing approvals for new medicines. This 'in-regulatory agency' not only grants permission to commercialise pharmaceuticals, it also delivers support for the provision of patents by the Brazilian National Industrial Property Institute and provides sanitary controls over pharmaceutical production.[61] Controls entail the production factories, the processes used, and the materials and technologies included in the final product. ANVISA also plays a role in medicines pricing decisions, as part of the marketing decisions.

As already stated, where governments have an ability to lower the prices of medicines and other health technologies, they are obligated to do so. So, if through an HTA a medicine is determined to be potentially too expensive, before rejecting inclusion into the public system, governments should investigate all means through which they may be able to lower the costs of those medicines, such as voluntary or compulsory licenses. This is particularly true in situations – such as the case in Egypt described just below – where there is a significant public health need within the poorest and most marginalised populations.

The case of Gilead and sofosbuvir in Egypt

Debate surrounding Gilead's recently introduced Hepatitis C treatment, sofosbuvir, is a good example of tensions around the prices of new medicines. In the United States, sofosbuvir is currently priced at $84,000 for a 12-week course.[62] Many US states, such as Oregon, are considering whether they can afford this therapy in their Medicaid programmes.[63] The price of sofosbuvir is even more of a problem for MICs, including Egypt, where the hepatitis C burden is amongst the highest in the world. In 2008, it was estimated that there were nearly 6 million people living with hepatitis C in Egypt (and likely to be disproportionately affecting the poorest and most marginalised populations).[64] In part due to public outcry and civil society action, Gilead negotiated a lower price, $900 for the 12-week course, with the Egyptian government.[65]

However, in order for the Egyptian government to provide sofosbuvir for all affected people, even at this discounted price it would need to spend $5.4 billion, which in 2014–15 amounted to about 80% of country's total spending on health.[66] Such costs are clearly unsustainable and put the country in a very

difficult position; although it has a responsibility to ensure realisation of the right to health, costs such as these present an immense barrier. While Egypt clearly needs to increase the resources it commits to health, in the near term the sofosbuvir scenario effectively asks it to choose between addressing a huge public health crisis and maintaining a functioning public health system.

MSF and the Liverpool School of Hygiene and Tropical Medicine reported that the medicine could actually be produced for $100 dollars per course.[67] This suggests there is room for the price to be lowered to a level that is affordable to countries with extremely high hepatitis C burdens, keeping in mind that originator companies must at least recoup research and development (R&D) investments when initially pricing innovative medicines.

- Responsibilities for the industry

Many important medicines for essential healthcare are already available in generic versions. However, when seeking the lowest prices for medicines still under patents, governments should consider pharmaceutical company investment in medicine R&D. Through tiered pricing schemes the pharmaceutical industry hopes to recoup the costs of R&D by charging higher prices in markets with a greater ability to pay – and less in those that have less ability, effectively cross-subsidising global R&D.[68] However, it is very difficult to determine the extent to which this is actually occurring because costs for medicines R&D are largely publically unavailable. Neither is there sufficient R&D of medicines and formulations for neglected diseases and those primarily affecting poor countries.[69] Therefore, alongside public and donor funding, pharmaceutical companies need to direct more of the income from sales to R&D for these products, particularly paediatric medicines, to be able to justify such schemes.

Pharmaceutical companies have a responsibility to ensure that prices are set in an equitable, transparent and participatory manner.[70] This will mean improving equitable pricing schemes so that they take into account more than just a country's national income in determining what price it should pay for any given medicine. Within the context of UHC in particular, companies must take into account the government's responsibility to progressively realise the right to health and the aggregate financial impact of introducing new medicines into coverage packages on national health budgets.

Implications of global health financing mechanism support (from GFATM, PEPFAR, Gavi and others) for medicines procurement in developing countries, graduation, etc.

In many LMICs, global support helps the purchase of new medicines and health technologies. In Vietnam, international donors provide the majority of funding for HIV, a significant component of which are costs of medicines.[71] Gavi provides significant support for vaccines in nearly all low-income countries. One key question that is now increasingly pressing is what happens to supply of these costly medicines when international support stops?

As the distribution of poverty changes, nearly 75% of the world's poor now live in countries classified as middle-income. Global health financing mechanisms must consider how their eligibility and graduation policies will enable them to provide support where health need is greatest and where it can be catalytic at ensuring sustainable access. Otherwise, there is the danger that many of the great global health gains that have been made over the last two decades as a result of this support will be lost.

The private sector has a role to play in this. For example, GlaxoSmithKline recently indicated that it would freeze prices on its pneumococcal, rotavirus and HPV vaccines for countries graduating from Gavi for a period of 10 years. Other vaccine companies have followed with similar announcements. These are helpful short- and medium-term actions, but more systematic action is needed to fundamentally address misalignment between global support mechanisms and where need exists.

Equally important is the fact that these organisations spend huge amounts of money on the purchase of medicines. About 20% of annual expenditure by the GFATM is on the purchase of medicines and pharmaceutical products.[72] 50% of Gavi's vaccines spending is on pneumococcal vaccine alone.[73] So for

their own sustainability as much as that of the countries in which they operate, it is incumbent upon these organisations to use their market-shaping power to promote generic medicines and health technology production and reduce prices. While Gavi, UNITAID, GFATM and others explicitly set out to do this, such as purchasing generic medicines, they need to do more to ensure their power makes prices sustainable for the long term.

It is also critical to reiterate here that generic medicines should be used whenever possible in the public system, so as to ensure the highest levels of efficiency. For example, France has implemented a strategy of generic substitution and it has been estimated that the wider use of generics saved €1.32 billion in 2008 alone, which was the equivalent then of US$1.94 billion.[74] The 2010 World Health Report suggests that steps countries can take include "improving prescribing guidance, information, training and practice; requiring, permitting or offering incentives for generic substitution; ensuring transparency in purchasing and tenders; controlling excessive mark-ups; and monitoring and publicizing medicine prices".[75]

Finally, as a matter of priority, countries should direct resources towards increasing their regulatory and pharmacovigilance capacity to ensure that as few spurious or falsified medicines are in circulation as possible. However, this should be done by improving regulatory capacity, either domestically or through regional pooling, and not poorly drafted and thought-out legislation that may have unintended effects. While spurious or falsified medicines are a cause for concern, these products should not be conflated or confused in any way with legitimately produced generic medicines. When purchasing such drugs, procurers must make sure to buy from a qualified regulatory authority, eg, WHO pre-qualified vendors where and when available.

- Strategic purchasing

The purchasing of medicines should fit into the broader context of purchasing for the entire health system. In order to best allocate the generated and pooled resources across this system, the WHO and others recommend that the government and other purchasers engage in 'strategic purchasing'. Strategic purchasing aims for the purchasers "to increase health systems' performance through effective allocation of financial resources to providers."[76] Strategic purchasing involves three sets of decisions:

- "Identifying the interventions or services to be purchased, taking into account population needs, national health priorities and cost-effectiveness".[77]
- "Choosing service providers, giving consideration to service quality, efficiency and equity".[78]
- "Determining how services will be purchased, including contractual arrangements and provider payment mechanisms".[79]

This paper has limited itself to an examination of the first category, namely priority setting. HTAs and similar mechanisms are tools meant to effectively determine and set priorities taking into account a broad set of concerns. The latter two decisions, choosing providers and determining how purchases will be made, though equally critical, lie outside the scope of this paper.

Regulation of medicines provision – addressing inappropriate use

Inappropriate use of medicines and health technologies require countries and other stakeholders to investigate many possible solutions. In many cases inappropriate use stems from lack of public services; under-investment in health workers; poorly trained providers; lack of adequate guidelines for use; lack of diagnostic equipment or ability; lack of safety monitoring or incentives, especially in the private markets, to prescribe particular medicines.

Alongside those problems, communities may have little information about or lack awareness of how to use certain kinds of medicines appropriately or they may be unable to regularly access dispensaries for physical or financial reasons, resulting in interrupted regimens. There is also likely to be a lack of

patient counselling on how to take medicines appropriately (particularly for vulnerable groups) and how to use certain health technologies. This is true for many children's medicines, which often require a calculation or the measurement of a dose of medicine based on particular factors. What is clear is that both the supply and demand sides will need to be addressed in order to adequately resolve the problem.

Regulation of antibiotic sales

Nepal provides a good example of AMR surveillance in a low-income setting. From 1998 to 2012, the Ministry of Health implemented a surveillance programme setting up a network of laboratories in order to analyse seven bacterial pathogens over time. The strengths of this programme came from its ability to enhance national surveillance capacity by applying standards and using protocols according to local needs. Last but not least, evidence gathered by this laboratory platform was effectively applied to national policies.[80] For example, results obtained from research on pneumococcal isolates (among which 20% were from children under five) were used to design a strategy on pneumococcal vaccination for children.

In Chile, the government also reacted quickly when evidence highlighting the overuse of antimicrobials was made available by introducing regulation measures on the supply side. While antibiotics could be purchased without prescription until then, the Ministry of Health limited their availability. They now can only be delivered through chemists and on prescription. This (at first unpopular) reform led to a significant decrease in inappropriate antibiotics consumption. This was made possible thanks to information campaigns directed toward both the public and providers, and the involvement of key stakeholders (civil society organisations, academic and professional associations).[81]

Experience from Tanzania also shows that involving private providers is crucial in the fight against AMR. The AMR initiative of the accredited drug dispensing outlets led to both an increased availability of antibiotics and improved dispensing practices, ultimately leading to more appropriate treatments. An interesting feature of the initiative was the education of providers, and information and counselling for patients about AMR challenges.[82]

Finally, surveillance is only part of the response and establishing access according to need rather than ability to pay is also crucial. [83] WHO, for example, recommends the inclusion of affordability in any strategy to control drug-resistant malaria, especially in Africa.[84]

In many if not most countries, private provision of medicines will continue alongside a UHC system. As mentioned earlier, people often first seek care from private providers for a variety of reasons including convenience (e.g., services available after hours), more respectful treatment, wait times, proximity and predictability of availability and will often choose to purchase medicines from private providers or dispensaries. Government regulation of private provision will therefore remain important. Incentives and regulations should be put in place to ensure that the private sector contributes to public health priorities and to public sector efforts to provide medicines within systems of UHC, particularly for poor and marginalised groups. And at the same time, all necessary steps need to be taken to improve all aspects of the public system in order to build public confidence.

Health system strengthening to improve access to medicines

As with health services, many factors play a major role in determining whether an individual ultimately has access to medicines and health technologies. Affordability, especially in systems in which most payments for medicines are out of pocket, will play a major role in determining whether a person has access. However, as countries begin to progressively realise the right to health and include more medicines within their public health systems free at the point of use, other health systems factors will begin to play an even larger role in access. These factors include:

- poor domestic distribution systems often leading to otherwise avoidable stock-outs

- physical or geographic barriers to access health services
- communities' lack of information, awareness or demand
- lack of appropriately and adequately trained healthcare workers
- low quality of medicines, including spurious and falsified medicines
- medicines unsuitable for resource-constrained settings
- lack of available information regarding the availability of or how to access particular health commodities and services
- unreliable medicines supply and distribution systems
- insufficient numbers of adequately trained prescribers and dispensers
- compliance and enforcement systems related to regulation of medicines
- perverse incentives for prescribers and dispensers.

Ultimately, ensuring access to medicines for all will require that each of these components of the health system is addressed as comprehensively as issues around affordability.

Conclusion and recommendations

Medicines, vaccines and other health products to be used directly by people have had a low profile in debates about UHC. Whereas paying direct cash to consult a health professional is increasingly accepted to be unfair as it deters the poor from accessing services and endangers vulnerable communities financially, similar considerations about buying medicines are raised less often. However, to ensure universal and equitable access to healthcare, to reduce financial impoverishment, to improve the health of populations and to reduce the harmful effects of misuse, medicines and other health technologies must also be brought under systems of UHC. As a starting point, Save the Children believes that all medicines on the WHO Model Essential Medicines List and those necessary for the RMNCH continuum of care should urgently be made available based on need and not on ability to pay, and that contributions to mandatory pooling mechanisms should be fair and equitable.

While essential medicines and health technologies are just one pillar of the health system, they are vital for child survival and for true progress towards UHC.

Recommendations

We call on governments to:

- commit to progressively include medicines under systems of UHC with the aim of making all RMNCH and essential medicines immediately available free at the point of use
- increase financing to pay for medicines and health products through mandatory contributions to pooled resources
- improve health systems to ensure access to medicines, including supply chain management, procurement and pharmacovigilance
- engage in strategic purchasing to ensure the most effective allocation of resources across the health system
- make use of all available tools to ensure that medicines and vaccines are procured at the lowest possible price through encouraging robust competition, use of generics, regulation, pooled procurement and use of TRIPS flexibilities where appropriate
- not undermine other countries ability to make use of these tools, such as through free trade agreements, to ensure access to medicines
- make use of health technology assessments or similar tools to make decisions on which medicines and health technologies are to be prioritised, taking into account both public health and human rights obligations and cost-effectiveness
- build sound drug regulatory and pharmacovigilance systems to ensure that quality medicines are appropriately controlled and used.

We call on the pharmaceutical industry to:

- improve tiered pricing policies in order to better take into account in-country equity and other public health-related considerations, and considering countries increased financial burden in progressing towards UHC
- make price information and pricing methodologies more available and transparent
- consider sustainable local manufacturing operations where these could improve affordability and availability
- increase research and development into new treatments that will benefit the most vulnerable and marginalised groups
- promote technological and know-how transfer, particularly quality assurance processes, in order to build all necessary capacity in middle-income countries and low-income countries for low-cost, high-quality local medicines production.

We call on civil society organisations to:

- advocate to governments to meet their human right obligations and progressively include medicines and vaccines in UHC systems that are free at the point of use
- scrutinise pharmaceutical company behaviour and encourage companies to make sure that their pricing systems are as transparent, equitable, fair and comprehensive
- identify when actions of government and the private sector threaten to restrict or are restricting access to products and scrutinise these actions
- champion the full use of all tools, such as TRIPS flexibilities, for governments and other stakeholders to ensure affordability and access to medicines generally
- champion the use of quality assured generics.

We call on multilateral organisations and donors to:

- support countries to develop sustainable, transparent and evidence-based financing mechanisms, including tax and mandatory insurance, and to move away from voluntary, small-scale pooling mechanisms
- engage in market-shaping activities to reduce the price of medicines and vaccines and promote the research and development of medicines for poverty-related and neglected diseases
- provide financial and technical support to countries so that they may improve their drug regulatory systems, medicines supply chains and other health system factors critical to ensuring increased access to medicines
- continue to improve graduation and eligibility criteria for countries in order to take into account the changing location of global poverty and public health need and to support countries based on public health need.

ENDNOTES

[1] WHO, What is universal coverage?, Available at http://www.who.int/health_financing/universal_coverage_definition/en/
[2] UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3.
UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations, ICESCR ratifications. Available at https://treaties.un.org/pages/viewdetails.aspx?chapter=4&lang=en&mtdsg_no=iv-3&src=treaty.
[4] UN Committee on Economic, Social and Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant), 11 August 2000, E/C.12/2000/4.
[5] World Health Organization. 2010. *World Health Report: Health Systems Financing: The Path to Universal Coverage*. pg. 40. *Available at:* http://whqlibdoc.who.int/whr/2010/9789241564021_eng.pdf.
[6] The World Medicines Situation 2011 - Options for Financing and Optimizing Medicines in Resource-poor Countries (2011; 68 pages). Available at http://apps.who.int/medicinedocs/documents/s20033en/s20033en.pdf.
[7] Bloomberg, "World Bank's Kim Says Heath Coverage Can End Poverty", http://www.bloomberg.com/news/articles/2013-05-21/world-bank-s-kim-says-health-coverage-can-end-poverty
[8] Bigdeli M, Peters D, Wagner A, Medicines in Health Systems: Advancing access, affordability and appropriate use, 2014. Available at http://www.who.int/alliance-hpsr/resources/ATMFlagshipReport.pdf?ua=1
[9] Alam M. and Tyagi R.P., A Study of Out of Pocket Household Expenditure on Drugs and Medical Services, October 2009 Available at http://planningcommission.nic.in/reports/sereport/ser/ser_drug2910.pdf
[10] UNICEF, Immunization Coverage and System Performance Indicator Data. Available at http://data.unicef.org/child-health/immunization#sthash.0V6AuJDd.dpuf
[11] See note 10.
[12] Ibid.
[13] Ibid.
[14] Ibid, pg. 62.
[15] Ibid.
[16] Ibid, pg. 63.
[17] Kamal Yanni, M, Salt, Sugar, and Malaria Pills: How the Affordable Medicine Facility–malaria endangers public health, Oxfam, October 2012. Available at http://policy-practice.oxfam.org.uk/publications/salt-sugar-and-malaria-pills-how-the-affordable-medicine-facilitymalaria-endang-249615.
[18] Review on Antimicrobial Resistance, Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations, Chaired by Jim O'Neill, December 2014, Available at http://www.jpiamr.eu/wp-content/uploads/2014/12/AMR-Review-Paper-Tackling-a-crisis-for-the-health-and-wealth-of-nations_1-2.pdf [last accessed 10.02.2015]
[19] Planta M., The Role of Poverty in Antimicrobial Resistance, J Am Board Fam Med. 2007 Nov-Dec;20(6):533-9, doi: 10.3122/jabfm.2007.06.0 [last accessed 10.02.2015]
Nweneka C.V., Tapha-Sosseh N. and Sosa A., Curbing the menace of antimicrobial resistance in developing countries, Published: 19 November 2009, Harm Reduction Journal 2009, 6:31 doi:10.1186/1477-7517-6-31
[20] World Health Organization. 2010. *World Health Report: Health Systems Financing: The Path to Universal Coverage*. pg. 64. *Available at:* http://whqlibdoc.who.int/whr/2010/9789241564021_eng.pdf.
[21] Foster D., The Economic Burden of Antimicrobial Resistance in the Developing World, in de J. Sosa A. et al., *Antimicrobial Resistance in Developing Countries*, New York: Springer, 2010
[22] MSF, Untangling the Web of Antiretroviral Price Reductions, June 2014. Available at http://www.msfaccess.org/content/untangling-web-antiretroviral-price-reductions
[23] TB Alliance, MDR/XDR-TB, http://www.tballiance.org/why/mdr-xdr.php
[24] World Health Organization. 2010. *World Health Report: Health Systems Financing: The Path to Universal Coverage*. pg. 64. *Available at:* http://whqlibdoc.who.int/whr/2010/9789241564021_eng.pdf.
[25] Foster D., The Economic Burden of Antimicrobial Resistance in the Developing World, in de J. Sosa A. et al., *Antimicrobial Resistance in Developing Countries*, New York: Springer, 2010
[26] Reynolds et al.: Attributable healthcare utilization and cost of pneumoniae due to drug-resistant Streptococcus pneumoniae: a cost analysis. Antimicrobial Resistance and Infection Control 2014 3:16.
[27] Zaidi A.K.M., Huskins W.C., Thaver D., Bhutta Z.A., Abbas Z., Goldmann D.A., Hospital-acquired neonatal infections in developing countries, The Lancet, 26 March 2005; 365(9465): 1175-1188
[28] Review on Antimicrobial Resistance, Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations, Chaired by Jim O'Neill, December 2014, Available at http://www.jpiamr.eu/wp-content/uploads/2014/12/AMR-Review-Paper-Tackling-a-crisis-for-the-health-and-wealth-of-nations_1-2.pdf [last accessed 10.02.2015]
[29] Nweneka C.V., Tapha-Sosseh N. and Sosa A., Curbing the menace of antimicrobial resistance in developing countries, Published: 19 November 2009, Harm Reduction Journal 2009, 6:31 doi:10.1186/1477-7517-6-31
[30] Nweneka C., Tapha-Sosseh N. and Sosa A., Curbing the menace of antimicrobial resistance in developing countries, Harm Reduction Journal 2009, 6:31 doi:10.1186/1477-7517-6-31
[31] Laxminarayan R. et al., Antibiotic resistance—the need for global solutions, The Lancet Infectious Diseases Commission, Published Online November 17, 2013, Available at http://dx.doi.org/10.1016/S1473-3099(13)70318-9 [last accessed 10.02.2015]
[32] See note 14.
[33] Carasso BS., Lagarde M., Tesfaye A., Palmer N., Availability of essential medicines in Ethiopia: an efficiency-equity trade-off?, Trop Med Int Health. 2009 Nov;14(11):1394-400. doi: 10.1111/j.1365-3156.2009.02383.x.

[34] Dong H., De Allegri M., Gnawali D., Souares A., Sauerborn R., Drop-out analysis of community-based health insurance membership at Nouna, Burkina Faso, Health Policy. 2009 Oct;92(2-3):174-9. doi: 10.1016/j.healthpol.2009.03.013. Epub 2009 Apr 24.
[35] Carrin G., Waelkens MP., Criel B., Community-based health insurance in developing countries: a study of its contribution to the performance of health financing systems., Trop Med Int Health. 2005 Aug;10(8):799-811,
[36] Parmar D. et al., Do community-based health insurance schemes fulfil the promise of equity? A study from Burkina Faso, Health Policy and Planning 2013;1–9, doi:10.1093/heapol/czs136
[37] WHO, The World Health Report 2010. Health Systems Financing, The Path to Universal Coverage. Geneva: World Health Organization 2010
[38] McIntyre D. and Meheus F., Fiscal Space for Domestic Funding of Health and Other Social Services, Chatham House, Working Group On Financing, Paper 5, March 2014,
[39] Chuma J., Mulupi S., McIntyre D., Providing Financial Protection and Funding Health Service Benefits for the Informal Sector: Evidence from sub-Saharan Africa, RESYST, Working Paper 2, April 2013, Available at http://resyst.lshtm.ac.uk/sites/resyst.lshtm.ac.uk/files/docs/reseources/WP2_financialprotection.pdf
[40] See note 6.
[41] MSF, *The Right Shot: Extending the Reach of Affordable and Adapted Vaccines, 2nd edition*, January 2015
[42] Ibid.
[43] W Gordon, A Jones and J Wecker, 'Introducing multiple vaccines in low- and lower-middle-income countries: issues, opportunities and challenges', *Health Policy and Planning*. 27 (suppl 2): ii17-ii26, 2012
[44] See note 41.
[45] Committee on Economic, Social and Cultural Rights, General Comment 3, The nature of States parties' obligations (Fifth session, 1990), U.N. Doc. E/1991/23, annex III at 86 (1991),reprinted in Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies, U.N. Doc. HRI/GEN/1/Rev.6 at 14 (2003).
[46] Ibid.
[47] See note 4.
[48] Save the Children, Tiered pricing: The global solution to access to medicines?, November 2015. Available at http://www.savethechildren.org.uk/resources/online-library/policy-brief-tiered-pricing
[49] Save the Children, Tiered pricing: The global solution to access to medicines?, November 2014. Available at http://www.savethechildren.org.uk/resources/online-library/policy-brief-tiered-pricing
[50] WHO, Medical Device, Health Technology Assessments, 2015. Available. at http://www.who.int/medical_devices/assessment/en/
[51] Mohara A. et al., Using health technology assessment for informing coverage decisions in Thailand, Journal of Comparative Effectiveness Research, Vol. 1, No. 2 , Pages 137-146, doi: 10.2217/cer.12.10
[52] Gorokhovich, Chalkidou and Shankar, Improving Access to Innovative Medicines in Emerging Markets: Evidence and Diplomacy as Alternatives to the Unsustainable Status Quo, Journal of Health Diplomacy, August 20, 2013, Stockholm International Peace Research Institute
[53] Wilsdon T., Fiz E. and Haderi A., A comparative analysis of the role and impact of Health Technology Assessment: 2013 Final report, Charles River Associate, Washington:2014
[54] Mohara A. et al., Using health technology assessment for informing coverage decisions in Thailand, Journal of Comparative Effectiveness Research, Vol. 1, No. 2 , Pages 137-146, doi: 10.2217/cer.12.10
[55] Ngorsuraches S., Meng W., Kim B.-Y., Kulsomboon V., Drug Reimbursement Decision-Making in Thailand, China, and South Korea, Value in Health, Volume 15, Issue 1, Supplement, January–February 2012, Pages S120–S125, Available at http://www.sciencedirect.com/science/article/pii/S109830151103539X [last accessed 12.02.2015]
[56] Teerawattananon Y., How HTA inform coverage decisions in Thailand, HITAP, Powerpoint Presentation, Prince Mahidol Award Conference 2012.
[57] Tantivess S., Health technology assessment and policymaking in Thailand, Regional World Health Summit, Asia, Singapore 2013. Powerpoint presentation.
[58] Gorokhovich, Chalkidou and Shankar, Improving Access to Innovative Medicines in Emerging Markets: Evidence and Diplomacy as Alternatives to the Unsustainable Status Quo, Journal of Health Diplomacy, August 20, 2013, Stockholm International Peace Research Institute
[59] http://www.who.int/medical_devices/Sat_am_HTA_4_LEMGRUBER.pdf
[60] Espinoza S. M. A., Health Technology Assessment in Chile: Reflections on a Slow Process, ISPOR Latin America Consortium, October 2013 Volume 1 Issue 4, http://www.ispor.org/consortiums/latinamerica/articles/vol1issue4_healthpolicy_english.asp
[61] ANVISA Website, Available at http://portal.anvisa.gov.br/ [last accessed 12.02.2015]
[62] Reuters, U.S. lawmakers want Gilead to explain Sovaldi's hefty price,.March 2014 Available at http://www.reuters.com/article/2014/03/21/gilead-sovaldi-idUSL2N0MI0UP20140321
[63] OregonLive, Clash between state, drugmaker heats up as Legislature takes up Hepatitis C cost, September 2014. Available at http://www.oregonlive.com/health/index.ssf/2014/09/clash_between_state_drugmaker.html
[64] Centers for Disease Control, Progress Toward Prevention and Control of Hepatitis C Virus Infection — Egypt, 2001–2012, Morbidity and Mortality Weekly Report, July 2012. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6129a2.htm.
[65] Reuters, U.S. lawmakers want Gilead to explain Sovaldi's hefty price,.March 2014 Available at http://www.reuters.com/article/2014/03/21/gilead-sovaldi-idUSL2N0MI0UP20140321
[66] Egypt Daily News, FY 2014/2015 state budget announced, analysts weigh in, May 26 2014. Available at http://www.dailynewsegypt.com/2014/05/26/fy-20142015-state-budget-announced-analysts-weight/

[67] MSF, MSF Access Campaign response to Gilead's deal with generic companies for sofosbuvir and ledipasvir, September 2014. Available at http://www.msfaccess.org/content/msf-access-campaign-response-gilead%E2%80%99s-deal-generic-companies-sofosbuvir-and-ledipasvir
[68] Daems R, Maes E and Ramani S, *Global Framework Differential Pricing of Pharmaceuticals*, UNU-Merit and MGSoG Working Paper Series, 2014, p 12
[69] All-Party Parliamentary Group on Global Tuberculosis, *Dying for a Cure: Research and development for global health*, 2014. Often this has been described as the 90/10 gap which describes pharmaceutical use and as compared to disease burden. While the accuracy of this number has been disputed, it is generally acknowledged that there is a great disparity between where investments in R&D are directed and health priorities as indicated by global disease burden.
[70] Save the Children, Tiered pricing: The global solution to access to medicines?, November 2014. Available at http://www.savethechildren.org.uk/resources/online-library/policy-brief-tiered-pricing
[71] Report of the Special Rapporteur on the right to health, http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-15-Add2_en.pdf
[72] GFATM, Funding and Spending, http://www.theglobalfund.org/en/about/fundingspending/
[73] Usher A, Gavi gears up for record replenishment, *The Lancet*, Volume 384, Issue 9939, Pages 219 - 220, 19 July 2014
[74] See note 14.
[75] Ibid., pg. 63.
[76] London School of Hygiene and Tropical Medicine, What is strategic purchasing for health?, October 2014. Available at http://resyst.lshtm.ac.uk/sites/resyst.lshtm.ac.uk/files/docs/reseources/Purchasing%20brief.pdf
[77] Ibid.
[78] Ibid.
[79] Ibid.
[80] Malla S. et al., The challenges and successes of implementing a sustainable antimicrobial resistance surveillance programme in Nepal, BMC Public Health 2014, 14:269, Available at http://www.biomedcentral.com/1471-2458/14/269 [last accessed 11.02.2015]
[81] Bavestrello L, Cabello A., How Chile tackled overuse of antimicrobials. Essential Drugs Monitor 2000; 13–14.,
[82] Valimba et al., Engaging the private sector to improve antimicrobial use in the community: experience from accredited drug dispensing outlets in Tanzania, Journal of Pharmaceutical Policy and Practice 2014, 7:11 Available at http://www.joppp.org/content/7/1/11 [last accessed 24.03.2015]
[83] Laxminarayan R. et al., Antibiotic resistance—the need for global solutions, The Lancet Infectious Diseases Commission, Published Online November 17, 2013, Available at http://dx.doi.org/10.1016/S1473-3099(13)70318-9 [last accessed 10.02.2015]
[84] Bloland P.B., Drug resistance in malaria, Background Document For the WHO Global Strategy For Containment Of Antimicrobial Resistance, World Health Organisation 2001, Available at http://apps.who.int/medicinedocs/documents/s16346e/s16346e.pdf [last accessed 11.02.2015]

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