



Médecins Sans Frontières

Campaign for Access to Essential Medicines

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Interviews and Essays

WANTED: New Ideas to Steer and Finance Medical Research & Development, and Ensure Access to Medicines

World Health Organization Director General Margaret Chan is right: the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) is a historic occasion, one that presents historic opportunities. But only if delegates get it right.

For the first time, the public health community is taking on the task of addressing the shortcomings in medical innovation today and the burdensome consequences of relying predominantly on patents to finance health R&D. The 1995 TRIPS Agreement globalised a R&D financing mechanism that is based on patent monopolies.

On the one hand, this system leaves us with a model for drug, diagnostic or vaccine development that is driven by commercial rewards, and leaves many pressing health needs unanswered. On the other, it creates monopolies and thus high prices for health products, accentuating barriers that prevent the poor from accessing life-saving medicines.

The shortcomings of the present system have been clearly set out for all by WHO's Commission on Intellectual Property, Innovation, and Public Health in its report in 2006, whose recommendations form the basis of the work of the IGWG.



Photo © Sofie Stevens/MSF

Médecins Sans Frontières witnesses the deadly effects of these shortfalls every day. When asked what tests, drugs, or vaccines are needed, and for whom, MSF field teams' wish lists are long.

Our doctors speak in this booklet of how they are unable to provide good care for people with tuberculosis, due to the lack of good diagnostic tools and drug regimens that everyday lose yet more of their effectiveness.

Our field programmes make do with what tools do exist for most neglected diseases, such as Chagas, but have to confront every day the inadequacy of drugs and diagnostics to help their patients. Despite the successes of treating HIV in the West, our HIV/AIDS projects are still desperately lacking tools for children, for women and for people infected with

both HIV and other diseases, like tuberculosis or malaria.

And when the tools do exist, MSF all too often struggles to access them – with devastating consequences. Our teams in Asia tell of patients going needlessly blind because of a virus – a treatable condition, but the exorbitant price of the best drug leaves it out of reach. Looking to the future, MSF's HIV programmes, heavily reliant on generic medicines from India, see their source of affordable drugs drying up as India now grants patents on pharmaceutical products – and with no sign of a strategy to address this looming problem. Worse, developing countries that attempt to make use of flexibilities in patent laws to increase access to needed medicines are met with harsh criticism and threats of trade sanctions from Europe and the USA.

The task ahead of the IGWG is quite considerable. It must work to strengthen access to medicines, and resist any attempts to derail the Doha Declaration – a text that clearly puts public health needs foremost. It must not restrict the scope of the IGWG's work to a limited list of diseases, but must prioritise real R&D needs in the developing world today and tomorrow, regardless of any predetermined lists.

And it must support alternative mechanisms to finance R&D that is driven by health needs. In 2007, the World Health Assembly asked the WHO to “encourage the development of proposals for health needs driven R&D for discussions at the IGWG that includes a range of incentive mechanisms including also addressing the linkage between the cost of R&D and the price of medicines, vaccines, diagnostic kits and other health-care products.”

The IGWG must explore the access and R&D initiatives on the table, and further their development to assess if they can succeed in bridging the gaps – and indeed in separating the payment for the cost of R&D from the price of the product. The IGWG cannot limit itself to providing extra money for medical R&D – it must also address the fundamental shortfalls of today's system: it must work to change the rules.

Médecins Sans Frontières urges IGWG delegates to respond to the Resolution. We urge you to translate the talk into action.

Dr. Tido von Schoen-Angerer
Director, Médecins Sans Frontières
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Calling All Governments: Put Patients' Needs First!

Dr. LIESBET OHLER, who works at the Médecins Sans Frontières clinic in Mathare, a slum in Nairobi, Kenya, talks about her frustrations and the lack of adapted, effective and affordable medical tools for treating her patients.

Charles, two and half years old, died recently. He'd been brought to the Médecins Sans Frontières clinic in Mathare, famous as the poorest slum in Kenya. His death makes me angry because, for all the will in the world, I simply could not give him quality care.

Charles was HIV positive and also infected with tuberculosis (TB). Here in Kenya, like elsewhere in Africa and throughout the developing world, we are struggling to treat and diagnose HIV/AIDS, including in children, struggling with TB, and with the rise of new strains of TB that are resistant to more and more drugs.

The scale of the response falls dramatically short of the needs. Doctors and patients are forced to use antiquated, unusable and sometimes unaffordable drugs, diagnostics, and vaccines, if these exist at all.



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We don't have the effective, adapted and affordable medical tools we need for one fundamental reason: the current way the development of health products

is financed. Today's research and development (R&D) system relies – with detrimental consequences – on companies recouping their R&D

investments by charging high prices for the drugs they market. And patents are what keep these prices artificially high. This doesn't just mean that some drugs

remain completely out of reach for many patients, like those in my clinic in Mathare. It also means that diseases that mostly affect the poor, like TB or paediatric HIV, don't attract nearly the same level of research or investment as diseases that have markets with bigger and better commercial prospects.

We now have an unprecedented opportunity to right this wrong. Government representatives from the world's Ministries of Health are exploring ways to change the R&D paradigm. The IGWG could reorient the medical innovation system and help provide hope.

Confirming Charles' HIV status was possible for us because MSF has access to high-tech tests that require skilled personnel, expensive equipment and a sizeable, dedicated lab. This makes the test unusable in remoter areas, where doctors can only guess if a child under the age of one is HIV positive.

But one cannot diagnose TB with accuracy or confidence: most diagnosis of TB involves using a procedure developed in the 1880s – that's right, the 1880s – examining a sample of a patient's sputum to see if it contains TB bacteria. But children are unable to produce sputum samples for examination, and interpreting an infant's chest X-ray is a specialist's job.

And if one does manage to get a child

like Charles's diagnosis right, treatment is the next hurdle, because there simply isn't any that is adapted. One of the primary antiretrovirals (ARVs) cannot be given to children who weigh less than 10kg, and its most common replacement drug won't do, because it interacts with the TB treatment. So either one has to give him suboptimal AIDS drugs, or adapt the TB treatment and give unsuitable TB drugs. This is not the sort of decision a doctor likes to face.

We need urgent investment into tools that may not have a profitable market – very few children have HIV or TB in rich countries, so the current R&D paradigm, relying on market incentives, is simply unable to deliver better tools to diagnose or treat children like Charles.

The IGWG has the mandate to set research priorities and has been told to design financing mechanisms that pay for R&D, but do not rely on charging high prices. Governments can change the current failing system by promoting alternative systems that reward R&D, not through the high price of medicines, but for the impact a new drug or test has on global health - on the lives of people like Charles. As a doctor fighting to treat HIV/AIDS and TB, I need medical innovation to happen.

The stakes are high. The TB drugs we have today are so ill-suited that treatment for standard TB lasts at least six months. This is much too long and

many patients give up. Half a million people develop multi-drug-resistant TB every year. The tiny proportion of those that do get treatment go through hell for two years, taking older, weaker and more toxic drugs with violent side effects. And the ARVs used for patients who are co-infected with HIV only make this worse. TB research has suffered from decades of neglect, and even today, the pipelines of prospective new drugs and diagnostics are not strong enough. A recent report by Treatment Action Group estimates the yearly funding shortfall at US\$800 million to plug these research gaps.

And crucially, as a doctor, I need to know that when new products are developed that could really make a difference in my patients' lives, they will be affordable. The IGWG needs to make sure that medical innovation doesn't happen at the expense of access to medicines, through widespread patenting of drugs and diagnostics that price them out of reach. Of course, essential R&D does need to be rewarded. But this cannot mean that access is rationed.



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The IGWG offers an unprecedented chance to address both medical innovation and access to medicines for diseases that take a massive human toll. Rarely in international health does such an opportunity present itself. We must seize the moment before it passes.

Dying For a Test: “We Need to Break the Cycle of Neglect”

Diagnosing tuberculosis has always been a complex affair, as much of the science on the TB bacillus still escapes us - and many of the tools are either antiquated and unreliable, or modern and too high-tech for use where they're needed most. Now that drug-resistant strains of the disease are rapidly spreading, and that HIV is pouring oil onto the fire of the TB pandemic, there is an urgent need for tests that can deliver accurate results, in the remotest settings, and fast.

We ask MARTINE USDIN, biologist with the MSF Access Campaign, what needs to be done for better TB diagnostics, and how IGWG can change the picture.

What are the biggest challenges today in diagnosing TB?

Diagnosing standard tuberculosis has always been difficult, and this is one of the reasons why TB is making such a comeback, because many people that needed treatment have been missed, and have gone on to infect others.

But the emergence of drug-resistant strains, when the TB bacteria have become resistant to some of the medications which are then no longer effective, has considerably complicated the challenges.



Photo © Remco Bohle

Are today's tests suited to these challenges?

No, in fact they are woefully unsuited. Existing tools, such as sputum smear microscopy, are very insensitive, which in practical terms means that fewer than half of the patients that have the pulmonary form of TB disease will be diagnosed, and none of the patients with other forms of the disease. But smear microscopy is the tool in widest use today, which is quite incredible given that it's a technique that misses more patients than it detects, and hasn't improved much since its development in the late 1880s.

Another technique to detect TB is culture, when you 'grow' a sample of bacteria. Culture is more sensitive than microscopy and can also tell you if the bacteria is sensitive to the drugs, but in its current form it's complicated to perform, requiring expensive equipment that is hard to maintain. Plus culture is slow - it can take weeks to months to get an answer. For patients with HIV and that are infected with resistant TB strains, most of them die before their DST results are available. Modified culture methods are being developed that are simpler and faster. But they are still not simple enough to make them useful in the most remote areas.

For patients with drug-resistant strains, you need to know which drugs work and which don't through drug sensitivity testing or DST. Otherwise you run the risk of giving patients drugs that simply won't do anything to treat them. Evidence shows that patients with drug-resistant TB who are treated inadequately with first-line drugs do very much worse than if you treat them with the correct drugs from the start.

Also, TB is the number one killer of HIV patients. But they are often too sick to produce a sputum sample for testing, or have the very severe extra-pulmonary forms of TB, which are also harder to diagnose. But these people are often the sickest ones, precisely the ones for whom we need a result quickly if we can hope to save their lives.

What are the critical characteristics needed for a test to be useful in remote settings?

We urgently need a test that identifies active TB disease. We also need to know the drug sensitivity pattern in that patient, at the time of diagnosis or very soon thereafter.

Ideally the test shouldn't require electricity or refrigeration. It must give an answer rapidly, preferably the same day, and that answer should be easy to interpret in a way that can then be used to directly influence the management of patients, for example a positive test means treat or refer to the clinic, and a negative test means no action. It needs to handle large numbers of patients per day. Of course, it must also be affordable.

The need for a test to detect active TB - when the person has the disease and is sick- is urgent. Much of the research into new tests is focused on tests that detect latent TB - when the person is infected but the bacteria are dormant. Detecting latent TB is only a priority for countries with few cases of active TB, which is the case of many Western countries. There is a potential wealthy market for such TB tests, so current commercial incentives are more likely to stimulate development of a new test to detect latent TB infection, when what we really need, what is far more urgent, is a better test for active TB.



Photo © Renzo Bohle

What are the main obstacles that are holding up the development of new tools?

We need more money, and that money should go to different sources. Today, funding for TB diagnostics development is mostly channelled through the product development partnership FIND, which has gathered a powerful team of accomplished minds to help develop products. But many more groups need to work on this. Also, FIND has chosen to focus on tests that can be commercialised – a model that has its merits but should not be the only one.

But it doesn't stop at money. TB is a hard organism to work with, making progress slow, and is not viewed as an important area of research, so scientists find it hard to find funding to tackle some of the fundamental research questions. There are

enormous gaps in our knowledge of many aspects of TB such as interactions between the host and the TB organism, how the bacteria survive in the body, what makes some people fall ill while others do not, and so on.

We need improved tools now, not in ten or twenty years. So we need to explore how we can optimise our current knowledge, for example by systematically evaluating combinations of antigens to develop a point-of-care test that works better than current tests.

What needs to happen now? What's your message for the IGWG?

We need to dare more, to ask for more. Things move so painfully slowly in the TB world, and we don't have the luxury of time any longer. If we had acted boldly 60 years ago, we would be in a very different place now.

I'd like to see the IGWG finally break this cycle of neglect and hesitation. We need more money, for a start, as TB diagnostics

only gets about 7% of what little money is allocated to TB research. Academics need more grant funding to push their research forward more sustainably.

The IGWG should also come up with solutions that encourage open access to results and sharing of knowledge, as a lot of work is duplicated by different groups, or is not done systematically because everybody works in their own corner.

But there is also a need to create rewards for groups that come up with a new point-of-care test. A prize might be an effective pull mechanism because you can define the specifications of a test, and 'reward' multiple steps along the way, and it can help ensure that the test will be affordable and accessible. It's critical that any financial rewards do not result in higher prices for the test.

Acting now is an ethical requirement so that we can better treat our patients. There is no time to waste.

“And the Winner is...”

How the Prize Model Could Help Deliver Needed Drugs and Diagnostics

JAMES LOVE, Director of Knowledge Ecology International, discusses how offering prizes represents an alternative to today's system that is based on patents and high drug prices to pay for research and development.

What kind of advantages could prizes present over the current system that relies on patents?

Prizes could present considerable advantages over product monopolies as the reward for drug development. There are some areas where prizes are particularly compelling. Many experts have said that prizes should be used to stimulate R&D for what the WHO calls Type II and III diseases – diseases that predominately impact low-income people living in developing countries.

Prizes should also be used to induce innovation for diagnostic tests and other medical technologies that should be nearly free at the point of delivery. In order to stimulate development of products that will be practically free, you need to de-link the reward from the product price. You offer a ‘prize’. When prizes are used to reward developers of



Photo © Nicolas Postal

new drugs and medical tools, it is easier to justify the open licensing of patent rights to generic suppliers.

And the development of antibiotics is another area where prizes could be used to eliminate the perverse incentives that

patent owners have to encourage the use of products, when such practices reduce the usefulness of products, due to

growing drug resistance. Newer antibiotics should be used only when older drugs don't work – but if you have a time-limited patent monopoly, you're going to want your new antibiotic to be used, whether it's needed or not. Prizes for antibiotic R&D could solve that issue.

Much of the industry scepticism over prizes is related to their concerns over the size of the reward. R&D is expensive, so if you want the prizes to induce innovation, they have to be pretty big.

How would the prize model work for TB drugs or TB diagnostic tests, for example? Have there been moves to get something like this going?

There is a great need for a rapid, low-cost TB diagnostic test that can be used in resource-poor environments. By definition, it has to be cheap, and normally a low product price would be a negative incentive for developers. There is also a need for new drugs to treat TB, but not much capacity to pay high prices for those drugs.

Barbados and Bolivia recently asked the WHO to consider the creation of a US\$ 100 million prize fund to reward the successful developer of a TB diagnostic test. It's a sophisticated proposal. It features a large prize of \$100 million for the successful development of a test that could be manufactured for less than \$1, provide results in less than three hours, have acceptable bounds for accuracy, and work in a resource-poor setting.

The proposal also includes a mechanism to encourage openness and collaboration, because the winning entrant would get 90% of the prize money, with the other 10% to go to scientists or engineers that have openly published and shared research, data, or technology, things that have made a great contribution to the end result.

Plus the proposal provided a mechanism to stimulate ongoing research. The idea is that while the challenge is still open and unfilled, the prize money would be invested in income-generating securities, and the annual earnings would be spent on a series of ongoing prizes to reward open and shared research that was helpful in developing the test.

Has the prize model worked before for innovation?

Yes definitely. In fact prizes are used extensively to stimulate innovation in very diverse fields, like mining, energy conservation, improving software, or agriculture, to mention only a few. Pharmaceutical company Lilly created a company called InnoCentive to manage prize competitions in the area of life sciences. We have collected a large number of such case studies in a Research Note called 'Selected Innovation Prizes and Reward Programs.'¹

But what would this model mean for intellectual property rights?

It's important to note that most proposals

for prizes do not do away with patents. The prizes either involve a voluntary license of patent rights, or they redefine the patent as a method of staking a claim against the prize money. You would still have patents, and patents would be valuable assets. But you would do away with monopolies. You don't need monopolies to stimulate R&D, and you don't need monopolies to reward drug developers. Prizes are a different and better system of getting money to drug developers.

Any new prize system will be implemented in a way that is consistent with TRIPS. This is not difficult, given the areas of flexibility in TRIPS, including Articles 30, 31 and 44, so long as the prize systems are adequately funded. For prizes that involve voluntary licensing of patent rights, such as the proposed TB diagnostics test prize fund, there is no conflict with the existing patent law systems.

What would be the first steps towards getting a system like this off the ground?

The World Health Assembly Resolution WHA60.30 and the WHO IGWG process have created an international forum for discussions about alternative R&D models, including prizes. It may take international cooperation to fund large prizes. But some countries are considering the use of prize-type rewards as an alternative to monopolies in certain key areas. For example, some countries have suggested de-monopolising all

cancer drugs, but providing a prize-type system to reward drug developers. Under these types of proposals, the prizes would be related to the impact of the cancer drugs on health-care outcomes. The size of the prize fund would be fixed at a proportion of the cancer care or drug purchase budget.

There is also a suggestion that donor programmes for AIDS, TB or malaria use prize funds to reward developers of new drugs, in return for a promise to voluntarily license patents to generic producers.

These and many other proposals provide opportunities to experiment with prize systems, with the aim of improving the delivery of both innovation and access to new medicines.

So what would you like to see out of the IGWG regarding prize funds?

The IGWG needs to schedule meetings to discuss the five Barbados and Bolivian prize proposals, and any other proposals that may surface. The IGWG needs to provide a place to move the conversation forward, and to encourage the WHO to undertake some real research in this area.

¹ KEI Research Note 2008:1. Available at www.keionline.org



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Is AIDS a Neglected Disease?

While millions are spent on HIV/AIDS research geared towards patients in the developed world, very little research is conducted to address the specific needs of populations infected with the virus in developing countries.

Dr. ALEXANDRA CALMY has worked in MSF's HIV projects in Mozambique, Malawi, Cameroon and Cambodia, and is a consultant for the MSF Access Campaign. She explains why HIV/AIDS in the developing world can be considered a neglected disease, what some of the most pressing needs are, and what needs to change.

Why do you call AIDS a neglected disease, when there is so much research going on?

The discovery of antiretrovirals (ARVs) and their combination into a complex triple regimen in 1996 was a real therapeutic revolution in HIV/AIDS, one that saved the lives of the people infected in wealthy countries. Now, the face of the epidemic has changed and there are more than 30 million infected, and 95% of whom live in developing countries.



When a disease affects developing countries, there's no commercial incentive, no trigger to do R&D. Without the R&D, treatment regimens, the management of HIV disease and delivery of care used in developing countries are just adapted from European and US

guidelines, without proper evaluation or adapted research.

But there are still so many challenges and we don't really know who will tackle them. AIDS is well studied, the funds are there and we have drugs that are more and

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more effective in the developed world. The epidemic in wealthy countries is stable. The flipside of this success is that some challenges for the West have disappeared – such as HIV/AIDS in children – leaving little incentive to develop new tools or work on adapting tools for developing countries, where the needs are different.

How are the needs different?

It's an entirely different HIV-infected population, in a different setting, in a different environment and sometimes with a different virus subtype.

Patients frequently also have TB, malaria or other infectious diseases, which are very different from what we see in Western countries. We don't exactly know how these diseases impact HIV and ARVs, and vice versa.

More than half of the people infected in developing countries are women – but very few studies have addressed the way AIDS drugs work in pregnant or lactating women. We don't exactly know how to treat TB in pregnant women with HIV, for example. Children are another critical issue. A child infected at birth needs years and years of treatment, but we just don't have the data, since very few children are infected with HIV in developed countries.

What we've learned and discovered in the developed world is a massive, great revolution, but we still don't have the answers to the big research questions in the developing world.

What about the tools? What tests and drugs does MSF need to be able to better treat patients with HIV?

AIDS requires life-long treatment, which means long-term management of the disease. In wealthy countries, every three months you do CD4 white blood cell counts, and also 'viral load' testing – to see how a patient is responding to treatment. You can't do that in Africa: it's expensive, and you need to send your viral load samples to a reference laboratory in the capital; there's a practical barrier.

We need easier ways to measure viral load, and CD4 counts. Without them, we can't know if a treatment is successful or not, we can't determine when a patient's therapy needs to be switched to a new therapy. And we need diagnostic tests that work in little babies; today we can't detect with a simple test whether babies under 18 months are infected or not when they are breastfed.

For drugs, we lack paediatrics drugs, and drugs that can be used during breastfeeding. We need certain drugs to be heat-stable, since many places don't have access to refrigeration. We need more fixed-dose combination options: for second-line treatment, for babies, as a once-a-day pill for pregnant women.

As you can see it's a long list of needs, and this just some of them.

What are the big difficulties in getting the best available drugs to our patients?

On one side is the access problem - the cost. MSF has mostly been using the most affordable triple fixed-dose combination treatment available. This was developed in India, because before India complied with the WTO TRIPS Agreement, there were no patents on the individual compounds there, so the manufacturers could make a generic three-in-one which really helped us treat many more patients.

But we now know other treatments are less toxic, so we've wanted to replace one of the drugs, stavudine, which can cause significant side effects, with tenofovir. The problem with tenofovir is the cost; it is more expensive than stavudine in part because there is less competition. We also do not have a generic three-in-one pill with tenofovir.

So the question then becomes: do you want to treat more patients on a more affordable combination, or do you want fewer patients on a better combination, but that is more expensive. It's a terrible kind of decision, but this is the reality for international funders today.

The other side is the delay issue, between the time a drug comes out in the West, and the time we get it to the field. We need the newer treatments to be made available to us quickly to treat

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our patients. But that takes us back to the R&D problem: what is really difficult is how to use these drugs, as they have not been properly tested in populations we treat. You cannot use a drug if you don't know how it will interact with pregnant women, with children... All this means there are often significant delays – years.

So what would you like to see governments address, as they look into the problems with the research and development system?

We run into the same R&D challenges for AIDS in the developing world as we do with diseases such as leishmaniasis or Chagas. Take HIV in children, it's a disease that doesn't really exist in wealthy countries. So there's little incentive to conduct research for a population that 'doesn't exist'. This

needs to change. Innovation that answers developing world needs has to happen. But we don't know who will pay for it; that needs to be addressed.

We're running into a wall when it comes to future AIDS regimens. Newer drugs will now be patented in places like India, where we source over 80% of our ARVs, as affordable generics. India has only been able to make these generics because the drugs were not patented there. But this is changing, and our source of affordable medicines is drying up.

This needs to be addressed urgently, there needs to be a plan to systematically use compulsory licensing to ensure the sources of generic supply are there and fixed-dose combinations can be developed and produced.



Photo © Cornell Botha

“Innovation Depends on Public Leadership and Not Just Public Funding”

United in their frustration at the lack of drugs for diseases that disproportionately affect the developing world, a group of five partners¹ from the public sector set up a product development partnership in 2003 – the Drugs for Neglected Diseases initiative (DNDi).

Their aim was to “address unmet needs by taking on projects that others are unable or unwilling to pursue.” DNDi has launched two new anti-malarial products the latest of which is a fixed-dose combination of artesunate and mefloquine (ASMQ), in April 2008. Importantly, ASMQ and its predecessor, ASAQ, are patent-free, and therefore can be made available as a low-cost generic immediately.

DNDi's Director Dr. BERNARD PÉCOUL explains why we need to rewrite the R&D rules, why giving more money is not enough of an answer.

¹ DNDi was co-founded by: the Oswaldo Cruz Foundation, Brazil; the Indian Council for Medical Research; the Kenya Medical Research Institute; the Ministry of Health of Malaysia; France's Pasteur Institute; Médecins Sans Frontières (MSF); UNDP/World Bank/WHO's Special Programme for Research and Training in Tropical Diseases (TDR) acts as a permanent observer.



DNDi has proven the success of its alternative model for drug development, so do the IGWG participants need to look any further for other models to create urgently needed products?

Definitely so. Since the inception of DNDi, we have always said that what we need to succeed in a sustainable way is public leadership. The Intergovernmental Working Group is a process involving all governments in trying to identify a framework and a long-term solution for innovation and access. In fact, the need for this strong leadership is stronger today than ever before.

What kind of leadership – do you mean funding?

Well, funding is one thing; for us funding is a primary responsibility of governments. We consider that public responsibility is key, so our fundraising policy is to attract a minimum of 50 % of our funding from governments. We have done so for this year but this commitment is not secure on a sustainable basis.

But government responsibility doesn't stop there. It can't be just about funding, the responsibilities are a lot broader than that. Governments must invest in needs-driven research and development to produce innovation, contribute to setting the agenda – and at the same time secure access to medicines for those who cannot pay for the drugs or vaccines. Innovation depends on public leadership and not just public funding.

So apart from sustainable funding, what would be the most important things that IGWG could deliver?

Firstly, reorienting the selection of priorities in the research and development agenda. I think governments and the inter-governmental sector (especially WHO) would probably be in the best position to coordinate this process and define the priorities - whether it's short, mid or long-term priorities. Because while you need to react to the immediate needs, you must also anticipate needs for the future, because if you are not investing now, you will not have the drugs and vaccines for tomorrow.

Secondly what IGWG can do is set up the rules of the game. When you undertake R&D to create innovation, you have to work within a very strongly regulated environment: firstly regulated by intellectual property rights – so the challenge there is to have access both to the knowledge at the beginning of the process, in the innovation phase, so that patents and other forms of intellectual property aren't a barrier in the R&D phase; and then also to secure access to innovation at the end, to ensure that the product is affordable so that patients can actually get the drugs, vaccines and tests.

The third major area where IGWG can have a positive impact is in the regulatory area around the registration of a product. Again, it's a public responsibility – regulatory authorities are linked to

government but they are crucial to stimulate and facilitate innovation and access. Regulatory authorities from disease-endemic countries are in the best position to measure the risk/benefit ratio for their own population. They need to be strengthened probably on a regional basis.

At the IGWG, there are concrete proposals on the table to open up access to the compound libraries which pharmaceutical companies keep, so that researchers could have early access to potentially useful molecules. How could that change the way that you work at DNDi?

We do this already at DNDi – we negotiate, case-by-case, with a company or with academic groups to have access to their compounds and to have the freedom to use these in our work to develop drugs for neglected diseases. It's a principle that we work with in all our negotiations with our partners. Our experience shows that this is a doable model to use but it is not ideal. It would help if access to

compounds was not dependent on a case-by-case process.

But our example should be translated into something much more formal in order to facilitate the process in the future and to act as a permanent stimulation of the innovation process.

If the IGWG negotiations simply delivered funding on a sustainable basis, would this be enough to solve the problem of lack of research into neglected diseases?

Funding alone will not be sufficient. You need the funding mechanism to be linked to an improvement of the rules because when you discuss funding, you have to discuss how much it will cost. If you only discuss funding without knowing about cost, you are in trouble because you are not capable of identifying the amount of money you will need to succeed.

Therefore, you need to set up a priority agenda with a number of essential drugs, vaccines and diagnostics, and you need to assess a reasonable cost for developing those products. Based on reasonable estimates of cost, you will then end up with the target of the financial resources that you need to attract to achieve your objectives. The final figures will be much less than the current figures that are floated (one billion Euros to develop a new product).

This will be an effective way to demonstrate that a new R&D model could be cost-effective for society.



Photo © Donald Weber

Falling Through the Cracks: Working to Fight Chagas Disease with Limited Tools

Chagas disease is caused by an insect that lives in the cracks of the mud hut homes of many of South America's poorest people. It affects an estimated 16 - 18 million people, and claims up to 50,000 lives a year.

Dr. JOSÉ LUIS DVORZAK and Dr. VICTOR CONDÉ work in six different MSF primary health clinics near Cochabamba, Bolivia, where among other tasks, they struggle to diagnose and treat Chagas patients with the inadequate tools at their disposal. Their wish list for new drugs and diagnostics is long.

Who are the people who come to your clinic?

Mainly poor people. Our patients suffer from a wide range of diseases: tuberculosis, diarrhoea, acute respiratory infections... and Chagas. The poor are at greater risk from Chagas, because the bug that transmits the infection lives in the wall cracks of their houses, as they're often made of mud or earth. When a family member is affected with Chagas, it becomes a major problem for the entire family, especially when the affected person is the main breadwinner.



Photo © Juan Carlos Tomasi

At public health facilities in Bolivia, testing and treatment for Chagas is free in theory, but it's not actually available in most clinics. Plus, there's no free treatment for adults. The only alternative for most people is expensive private medicine. So they come to us.

What are some of the difficulties associated with diagnosing Chagas disease?

The first major difficulty is that Chagas is

infection, and have never been diagnosed.

About 20-30% of those infected will go on to develop the chronic form of the disease, as much as ten or twenty years later. Most people we see were infected years ago, or even when they were children. By the time the chronic disease activates, patients may have developed lesions that cause irreversible damage to the heart and digestive system. At that point, treatment with the current anti-Chagas drugs is no longer effective.

The second problem is that the diagnostic tools we have to deal with this situation are far from ideal. The tests that give the most precise results are complex ones that require multiple blood tests. And this means you run the risk of losing the patient, because they won't come back, which is a big risk especially when someone isn't showing any symptoms. So what we use is a rapid test, which is far from perfect, but is the best screening tool. If the test is positive, the patient gets the blood tests to confirm the result.

There is also a major issue around diagnosis of cure, because we don't have a tool that tells us whether someone is cured or not.

often asymptomatic, which means that during the first acute stage of the disease, immediately after a person is infected, there are often no apparent symptoms. Children may show some symptoms, but these can be confused with those of other common childhood illnesses. At later stages of the disease, people do not show symptoms at all. So this means they are never diagnosed. Millions of people are in fact carrying this

Dr. Víctor Condé:

“I got to know a 17-year-old teenager who suffered from a Chagas-related advanced cardiopathy that needed to have a permanent pacemaker implanted. His heart problems meant that it was too late for him to benefit from specific Chagas treatment, but we managed to get a free pacemaker for him. But, just as we were about to go ahead and operate, the patient changed his mind, wrongly advised by those closer to him.”

What about treatments: are they available and how effective are they?

Oral benznidazol is the first choice treatment. If the patient suffers too much from the side effects, we replace it with nifurtimox, but that causes very frequent side effects, too. The side effects include allergic skin reactions that can be very severe in rare cases, and even fatal. There is also the risk of nerve damage and gastro-intestinal problems.

Both treatments take a considerable amount of time – 60 days – and must be taken under medical supervision. None of this makes treating Chagas an easy affair. What's worse, neither of these drugs is sufficiently effective to eliminate the parasite during the chronic phase of the disease. So the success of the treatment depends on how advanced the disease is and how it evolves. Patients who have recently been infected, usually children,

show cure rates higher and faster than patients who have had the disease for a long time. We can say that cure rates may be around 60-80% of cases at an early stage of the disease, although this seems to vary widely in different contexts, and we cannot really be sure because there hasn't been enough research. In chronic cases, that cure rate falls to below 50%.

Dr. José Luis Dvorzak:

“I especially remember a 24-year-old young man suffering from a Chagas-related severe cardiopathy with symptoms such as syncope and palpitations. He came to the clinic asking for benznidazol, believing that this would solve his heart problem, when in fact what he really needed was a pacemaker.”

Another issue is that there are still no paediatric versions of these drugs available. Instead, what we have to do is crumble adult tablets to give to children. But this is not an accurate or satisfactory way to treat our patients.

Basically, we're making do: the treatment is effective enough in both children and adults to make it worth using. But it's not nearly effective or safe enough to accept as the only option... that's why we need more research. The problem is, there isn't enough commercial incentive to ensure that happens.

**What would you like to see happen to improve the situation?**

There have to be much higher budgets allocated to the research of drugs that could help our patients in more effective and less risky ways. We have a long list of needs. We need a shorter treatment course, drugs with fewer side-effects, and drugs that don't require as much close medical supervision. These drugs need to be affordable immediately when they come onto the market.

Of course we also need paediatric versions of the drugs. We need better diagnostic tests that are effective at all stages of the disease, so that we can catch the disease at a stage when it can most effectively be cured.

And we need tests that can tell us whether someone has been cured or not, without having to wait 10-20 years to find out. This last one is very much a vicious circle, because it is very hard to test new treatments when you have to wait so long to find out if they work or not.

Advance Market Commitments: Are They Worth the Hype?

An Advance Market Commitment (AMC) is a financial mechanism that creates incentives to attract investment by the pharmaceutical industry into areas where the commercial rewards of the market are lacking. The GAVI Alliance pilot AMC, designed to deliver pneumococcal vaccines to the developing world, has already secured colossal donor funding and attention, including from the G8. But is it all that it's cracked up to be?

LAURENT GADOT, health economist with MSF, looks at the design of the AMC pilot, and in light of the IGWG, assesses the possible contribution of AMCs to the field of medical R&D.

In 2007, a World Health Assembly Resolution called on the WHO Director-General to encourage the development R&D funding mechanisms for discussion at the IGWG. These were to include proposals that address “the linkage between the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products”.

One example of a desperately-needed health tool is a new vaccine against pneumococcal disease. Over one and a half million people, most of them children, die each year of pneumonia, bloodstream infections and meningitis caused by pneumococcal bacteria.

A vaccine against pneumococcal disease,

appropriate to the forms of the disease prevalent in rich countries, has actually been available for use in those countries since 2000. But as it doesn't target several of the strains of the disease prevalent in developing countries - where the largest burden of the disease lies - it is of little use to patients there.

Eight years later, we are still waiting for a new generation of pneumo-vaccines that can be used widely in Asia and Africa. Fortunately, new products – from Glaxo-SmithKline (GSK) and Wyeth – should be launched in the coming years. Any initiative that aims to get these important vaccines deployed in poor countries as soon as they come to the market in wealthier ones is therefore to be welcomed as an important contribution.



The donors that have pledged to finance GAVI's pilot pneumo-AMC will meet in May 2008 to finalise the deal. Yet many questions about the pilot AMC remain unanswered.

A US\$ 1.5 billion carrot to industry

The main question obviously is the US\$ 1.5 billion price tag. Could it be done for less? When the initial design of the pneumo-AMC was released in 2007, MSF commented to the GAVI expert group that the design of the AMC would generate a sizeable windfall to industry – around US\$ 600 million of extra profit – beyond the standard profit required to attract investment.

In other words, US\$ 1.5 billion of public donors' money would be going towards a project that could happen for around US\$ 900 million, and still generate a fair profit to industry. Many inadequacies are apparently currently being addressed as GAVI embarks on a redesign process – but the carrot to industry is still as big.

For the most part, the AMC does not have to recoup the industry's R&D costs. GSK and Wyeth's new generation vaccines are approaching the end of development, so these costs are largely paid for – and their vaccines will be marketed in rich countries, so the firms can expect to see their R&D investment rewarded from sales there. The AMC would have to be attractive enough to act as an R&D incentive though for emerging suppliers, as their candidate vaccines are still far

away from licensure. But their products will be launched much later – and as such much of the money in the AMC pot is likely to have been claimed.

Nor is the US\$ 1.5 billion paying for the cost incurred by the firms to produce the goods. Under the terms of the AMC, developing countries that purchase the vaccines will be asked to pay US\$ 1-2 per dose – and this is roughly equivalent to GAVI's estimate for the cost of production.

For GSK and Wyeth then, the AMC is not paying for the cost of R&D or production. It is only aimed at paying back companies for their investment in production capacity, acting as an incentive for the firms to dedicate sufficient production of vaccines for supply to poor countries.

So why such a hefty subsidy? The experience of another new vaccine initiative shows how much can be done – and for much less outlay. The conjugate meningitis A vaccine is being developed through grants for a total of US\$ 70 million (a sum which pays for the R&D), and the products will be marketed at US\$ 0.40 per dose.

When too much is not enough

Despite all this, GAVI has warned that the AMC subsidy might still not be attractive enough to get firms to participate. Does the carrot need to be so big for companies that they need to see marketing the vaccines in poor countries

as a profitable venture on a par with marketing a blockbuster vaccine in rich countries?

It should be enough to reward companies participating in the pilot that the AMC provides a fair and positive return on investment. But if the firms stay away, it suggests that the high price of health products in rich countries acts as an indirect but powerful barrier to access to medicines in poorer countries, where the rewards cannot hope to compete.

Governments on the other hand may find it relatively easy to commit to AMCs. After all, within an AMC, donors do not have to pay if the industry fails to deliver the vaccines according to pre-determined specifications. But that aversion to risk is costly: as donors will only pay if eligible countries actually order a product, suppliers will ask for a higher price to compensate for that risk – legitimately so. Some form of advanced purchase commitments, which guarantee purchase, would be a more cost-efficient and simpler mechanism to convince suppliers to invest in the necessary production capacity.

Urgent need to review the price tag

As a proposal that seeks to make urgently needed vaccines available in developing countries, the pneumo-AMC must be welcomed, and the latest configuration of the AMC pilot is undoubtedly a step in the right direction to improve the design. But the economic simulations on which

IGWG – Advance Market Commitments

GAVI's expert group bases its recommendations must be made public in order that we may properly assess if the AMC can be implemented with significantly less money. Until that happens, the real mechanism of the AMC remains opaque.

Addressing the linkage between cost and price

As one of the funding mechanisms on the table at the IGWG, to what extent do advance market commitments answer to the Resolution's call? That AMCs seem to have the wind in their sails may be because they are only a minor adaptation of the present patent based market-driven system. They neatly sidestep any of the complex issues about intellectual property and R&D, and the need for health products offered at radically lower prices.

Governments should recognise that in developing policies for essential health R&D, we need to go well beyond the support for AMCs. Other alternative financing mechanisms, such as prize funds or an R&D treaty, may be better suited to solve problems of access to medicines and neglected disease R&D.

The IGWG is expected to promote alternative financing mechanisms – particularly ones that address the link between the cost of R&D and the price of products developed. The AMC, which does not address that link, cannot be the only proposal on the table.

'Outrageous' Cost of Medicine Condemns AIDS Patients to Blindness

Many patients with advanced HIV/AIDS can fall prey to the infection, cytomegalovirus (CMV) which will if untreated, lead to total and irreversible blindness in a very short space of time – sometimes just weeks.

Blindness caused by CMV is preventable, but the most available treatments are invasive and far from ideal – injections directly into the affected eye or intravenous, twice-daily treatment requiring a long stay in hospital.

There is a better medicine available – an oral medication, valganciclovir, produced by Roche. This drug is patented in China and the company charges US\$ 10,000 for a four-month

supply – simply too expensive for the vast majority of people most at risk of going blind. It's a similar situation in both India and Thailand – both middle-income countries where the product is patented. While the manufacturer offers discounts to the poorest countries – mainly in sub-Saharan Africa – middle-income countries including China are offered no such discount and are charged the same as wealthy countries.

Dr. PETER SARANCHUK has worked in China in both of MSF's HIV projects – in Nanning and the recently closed XiangFan project treating patients with HIV/AIDS. He describes his experiences in treating CMV and the frustration of seeing patients suffer because the best medicines are unaffordable.

What happens to patients with CMV?

If CMV infection attacks the person's retina and is left untreated, they will become blind over a period of weeks to months. This blindness is irreversible. CMV infection can also attack other parts of the person's body, such as the gastrointestinal system or brain. Such systemic CMV infection is serious, and without

treatment, will progress and invariably result in death in a person whose immune system is weakened by HIV.

How do you treat CMV in the MSF clinics in China?

In MSF's Xiangfan project, the treatment for CMV retinitis (infection of the retina) involved weekly injections of the



Photo © Dr. David Herden

medication ganciclovir, directly into the patient's eye or eyes if both were affected. The injections would usually be given for three to four months, depending on how quickly the person's immune system could be restored with medications to fight HIV. As you can

imagine, patients did not like to receive these injections, and would sometimes not return for the rest of their needed treatment. Additionally, there was a risk that other infections could be introduced to the eye during this procedure and the eye could bleed.

In MSF's Nanning project, instead of eye injections, a person is usually admitted to hospital for a prolonged course of the medication foscarnet, given intravenously. The hospitalisation lasts many weeks, and costs thousands of dollars for a single patient. Since few patients can afford such treatment, MSF covers the cost for people attending our Nanning clinic. But poor CMV/HIV patients in other Chinese settings usually receive no treatment and simply go blind.

An oral version of the treatment is available – what are the advantages of oral valganciclovir over the other treatments you have mentioned?

Oral valganciclovir is by far the best treatment available for CMV disease. Of course, as an oral medication, patients are much more likely to adhere to their full four month treatment and not default as when faced with the ordeal of direct injection of other drugs into their eyes. The oral medication also tackles the virus causing disease elsewhere in the person's body and not just locally as is the case with the directly-injected ganciclovir. And using oral valganciclovir means that the patient can usually be treated on an outpatient basis and does not have to be hospitalised.

With such obvious advantages, why is treatment with oral valganciclovir restricted?

The product, produced by the pharmaceutical company Roche, is available for purchase in China, but the

company charges the same amount as to customers in rich countries: each tablet costs about 275 RMB (or about US\$ 40). Since a treatment for CMV disease usually consists of 264 tablets given over four months, this means a total cost of over US\$ 10,000 just for the oral medication.

So unfortunately, the outrageous cost of this medicine prohibits its use in the people who need it most. The exorbitant price has also prevented the introduction of screening programmes in HIV clinics for CMV retinitis because nobody wants to screen for a disease when the treatment is out of reach financially.

"After my first injection... when I left the clinic the wind was blowing very hard and my eyes felt as if they were going to explode. I just could not hold my tears. I kept having pain for the whole week and before the pain was gone, I had to receive another injection."

Dou, a CMV patient from XiangFan in Central China.

How viable are the treatment alternatives to oral valganciclovir for patients in China?

The main treatment alternative is a lengthy hospital stay for daily intravenous medications (ganciclovir or foscarnet), which results in a similarly shocking cost for treatment. If the patient and/or his family is unable to afford this – and they often go into serious debt trying to do so – the patient goes without treatment, as the cost of health care is usually the

responsibility of the individual. MSF has thus far provided the treatment for free to patients with CMV disease in our Nanning clinic and previously in our Xiangfan clinic, as well. But we need to see the price for valganciclovir, drop drastically and very soon, in order to continue preventing unnecessary blindness and death in our patients suffering from CMV retinitis and systemic disease.

Roche offers discount prices for its product in the poorest countries but not in China?

That's correct. Right now, there is no company discount that we can access in China. For treatment to be accessible to patients who would benefit most from its use in many different settings around the world, a four-month treatment with valganciclovir should cost no more than US\$ 500.

Photo © Joanne Wong



A patient demonstrates the length of the needle used to inject ganciclovir directly into her eye

Monopoly position shuts out more affordable treatments

The pro-drug valganciclovir manufactured by Roche is patented in China. This means that Roche enjoys a monopoly position on the drug which will last until the patent expires in 2015. Until then, there can be no competition in those countries from generic companies to drive down the price of this medication. Meanwhile, many more will be denied the best treatment that could save their sight.

MSF approached Roche and asked them to make the drug more affordable for CMV patients everywhere. Roche came back with an offer of around US\$ 2,000 per treatment at current exchange rates – still way beyond reach for most patients in developing countries.

Further, the offer is restricted to use for MSF and other NGOs – governmental sector health programmes are excluded from the deal. In addition, the lower price applies only in the least developed countries and sub-Saharan Africa.

What lies behind Roche's unyielding position is the intent to protect its market for this drug in countries where it is used both for prophylaxis and in the treatment of CMV in transplant patients. The market for this is considerable – on average seventy thousand organ transplants are carried out each year.

DOHA Derailed

The World Trade Organization (WTO) rules specify how countries can overcome patent barriers by issuing compulsory licences and using other TRIPS flexibilities enshrined in the 2001 Doha Declaration on TRIPS and Public Health.

Yet recent attempts to exercise these lawful rights have been met with a barrage of criticism. MARTIN KHOR, Director of the Third World Network, tells us why, and what that means for the IGWG.



Photo © Christian Schwertz

What did the Doha Declaration concretely change for developing countries?

The Doha Declaration confirmed that all countries have the right to make use of flexibilities like compulsory licences (CLs). This allows them not only to produce generic versions of patented drugs, but also to export them under certain conditions.

This was an important step because, before Doha, when developing countries tried to implement their rights to give healthcare to their populations, they were subjected to political pressure – particularly by the United States or by the drug companies, for example in South Africa in 1998. So developing countries are now more confident that they can implement their right without any political pressure.

But don't recent events in Thailand show that using the Doha Declaration flexibilities attracts exactly that kind of political pressure?

Malaysia was the first country to implement CLs for three AIDS drugs. They did face a little bit of pressure but the government stood firm. After that, Zimbabwe, Indonesia, Ghana, Thailand and Brazil followed suit.

In the case of Thailand, I think that the companies were upset as it is the first time a CL was issued by a developing country not only for antiretroviral drugs, but also for other health problems such as cancer and heart disease. They fear the use of CLs may spread from HIV/AIDS drugs to other health problems.

Is there a restriction on the scope of diseases in the Declaration?

The issue came up at Doha: should CLs only be used for HIV/AIDS and maybe two or three other diseases? But developing countries put up a big fight that there should be no restriction in the scope of diseases. And they succeeded.

And Doha does not say there has to be a “medical emergency” for a country to be able to implement a CL. There are many reasons under which you can issue a CL. Under certain conditions, like in Thailand for non-commercial public purpose, when a government is itself getting the drugs and using in its hospitals, then the government need not negotiate with the patent holder beforehand. Thailand is within its rights. The reaction shows how developing countries are facing the threat of a political backlash, even if they carry out the compulsory licence in a totally legal way.

Issuing a CL requires a lot of knowledge of international and trade laws and this is a real challenge. What is not acceptable is that on top of these difficulties comes a political dimension: if you exercise your human rights, Western governments and pharmaceutical companies will use methods to punish you. This is something that frightens the developing countries. They are frightened to displease Japan, the US, the EU. That puts a clamp on these countries' ability to take measures for public health.

It's worth remembering that the EU and the US are agreeing that what Thailand did was according to the WTO rules. Peter Mandelson, European Commissioner for Trade, had to agree that Thailand was within its rights, even though he had written letters to the Thai government asking them to cease their CL action.

What does this mean for IGWG? What would you like to see coming out of the IGWG process in terms of concrete developments regarding access to medicines through Doha?

The IGWG was set up to reflect on the CIPIH report recommendations and take action. The report deals with intellectual property, R&D and access to medicines. Where drugs are available, how can we make sure that people can access them at an affordable price? And when they are not yet available, how do we invest more in R&D and how do we make them accessible for people once they are manufactured?

One major challenge is intellectual property rights – they can help innovation, but can also be abused if the monopoly is used not only to recover the costs of R&D, but to retain a very high price or to exclude others from making use of the knowledge. We must have a balanced approach to IP rights, to make sure they serve the needs of public health, rather than just creating and maintaining monopolies.

Also, a lot has changed since Doha. Many free trade agreements (FTA) have been signed or are being negotiated, and they can undermine the use of the Doha flexibilities. The CIPIH report recommends that countries shouldn't be encouraged to enter into FTAs that will restrict their policy space and their use of TRIPS flexibilities, and it urges the WHO to give the right advice to countries. That is a very good recommendation that could be moved to action by IGWG. That is the role of the WHO: support the ministries of health so that they can bring up the issue in their own countries.

Any other concrete measure that you see coming out of the IGWG?

One issue has come up at the WHO through the controversy over making a vaccine by using the avian 'flu viruses. To develop a vaccine, you need the latest genetic material from the virus – this belongs to the country of origin, which then should determine access and terms of use of the virus.

Indonesia realised that while they shared their viruses freely with WHO designated laboratories, some were given to companies which used them to develop vaccines which were commercialised for profits.

Developing countries want a benefit sharing agreement. In return for sharing their virus, they want access to the vaccine and diagnostic tools. At the moment this is not the case – they are

asked to pay very high monopoly prices for vaccines. The situation would be even more critical if there is a pandemic, as the global production of vaccines is very limited.

This is the subject of discussion in another working group within WHO, but many key issues are similar: access to affordable medicines and vaccines, R&D that ensures access to the final product, impact of intellectual property on upstream research, building capacity of developing countries through transfer of technology and know-how... The influenza virus sharing case provides an opportunity to explore the problems concretely, and to find new innovative solutions.

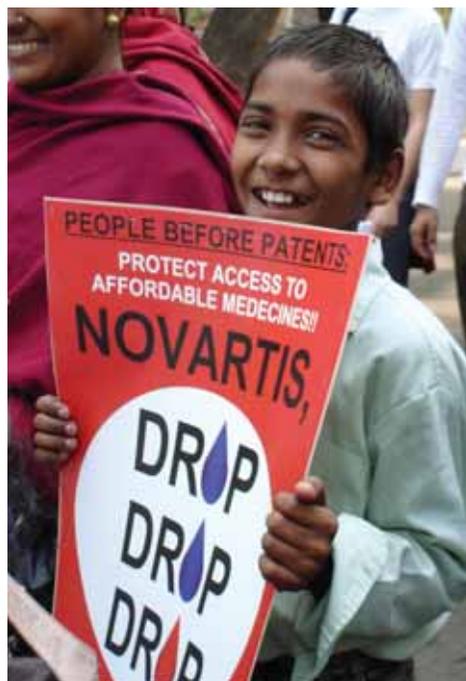


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The following topics have been covered in this booklet:

Dr. TIDO VON SCHOEN-ANGERER:

WANTED: New Ideas to Steer and Finance Medical Research & Development, and Ensure Access to Medicines

DR. LIESBET OHLER:

Calling All Governments: Put Patients' Needs First!

MARTINE USDIN:

Dying For a Test: "We need to Break the Cycle of Neglect"

JAMES LOVE:

"And the Winner is..." How the Prize Model Could Help Deliver Needed Drugs and Diagnostics

Dr. ALEXANDRA CALMY:

Is AIDS a Neglected Disease?

Dr. BERNARD PÉCOUL:

"Innovation Depends on Public Leadership and Not just Public Funding"

Dr. JOSÉ LUIS DVORZAK and Dr. VICTOR CONDÉ:

Falling Through the Cracks: Working to Fight Chagas Disease with Limited Tools

LAURENT GADOT:

Advance Market Commitments: Are They Worth the Hype?

Dr. PETER SARANCHUK:

'Outrageous' Cost of Medicine Condemns AIDS Patients to Blindness

MARTIN KHOR:

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