



**Collection Title (Bold Arial 10pt)**

*Mind the Medicine Gap*

**Keren Bright (narrator)**

I'm Keren Bright of the Centre for Law at The Open University and this programme is about global access to medicines. The principle is simple - that is, in terms of human rights we all have the right to health and we should all have the same access to medicines. However, the principle might be simple, but the issues operating against this are highly complex.

**Vanessa Babbage**

Hello my name's Vanessa and I live in South East London and I'm 44 years old. I was diagnosed with breast cancer in June 2008 and I was 42 years old then.

**Keren Bright**

One issue is around the relative cost of medicines and the impact this has on lives. Let's take two women in two very different parts of the world with stories to tell about being ill and getting treatment.

**Vanessa Babbage**

'After chemotherapy I had surgery followed by fifteen treatments of radiotherapy followed by the treatment of a drug called Herceptin. The Herceptin treatment, which runs over a year, which is eighteen treatments over a year, cost the NHS twenty six thousand pounds and each treatment of chemotherapy roughly costs about seven, eight hundred pounds'

**Keren Bright**

Meanwhile in rural Ethiopia a 19 year old woman waits in the health centre...

**Lemlem Gessese**

'My name is Lemlem Gessese, I live in Mojo Town. I work for a strawberry packing plant called Inlatout. When I felt headache they told me now that it is typhoid and typhus and he prescribed three types of medicine. Then I bought the three medicines home, thirty birr.'

### **Keren Bright**

So while Vanessa was able to obtain her treatment for free using the National Health Service in Britain, Lemlem Gessese had to buy the medicines she needed to treat typhoid and typhus and as she earns just over seventeen pound a month, the medicines cost, at one pound forty, more than two days pay.

### **Dr Mohga Kamal Yanni**

We know from the poor people that we work with that most of the income is not used where they want it to use be used like buying food or making their business work or expanding their business, but it's actually used on buying medicines. That's where our contribution can be; by raising awareness and saying 'hey, you know, this global system that's designed in London or Washington and Geneva actually doesn't work for these poor villages.

### **Keren Bright**

This is Dr Mohga Kamal Yanni, senior health and HIV policy advisor for Oxfam. She thinks a key problem is the current patent system.

### **Dr Mohga Kamal Yanni**

Medicine is different from any other goods. It's not like cars or washing machines or films. The price of medicine is very, very critical for millions and millions of people all over the world so patent tend to create monopoly and monopoly tend to create higher prices making medicine unavailable or unaffordable for people and that can't be right.'

### **Keren Bright**

On the other hand many would say that the current patent system is the *only* one that can deliver medicines effectively. Here's Jon Pender, Director of Government Affairs, Global Access Issues and intellectual property at GlaxoSmithKline.

### **Jon Pender**

'Well I agree medicines aren't like cars and washing machines and other consumer products. They literally are a matter of life and death for some people. That's why it is so important to continue to invest in research and development for new medicines and vaccines and cures. The only model that's been really proven to work on a large scale has been the intellectual property based R&D model. It takes on average ten to twelve years, costs are between five hundred million and a billion pounds, including the cost of failure, to develop a new medicine

and very few medicines are ever successful. So it's only the period of exclusivity that a patent provides that enables us to continue to generate the funds for ongoing R&D for medicines for the future.'

### **Keren Bright**

But a highly undesirable outcome of the current patent system is that pharmaceutical companies overwhelmingly make medicines for diseases with large markets – typically those of richer countries. They are much less likely to make medicines for diseases with small markets. These are the so called neglected diseases of tropical areas such as Lemlem Gessese's part of Africa. There is demand, but many could not afford to buy the medicines.

So while it's true that states have the primary duty to deliver the human right to health and widen access to medicines, companies that own patents do have a role to play too.

### **Paul Hunt**

They've got something incredibly valuable. It enables them to make a profit but they can't just conceive of these patents, as someone once described them, as 'crown jewels'. They're not crown jewels at all in the sense of something they can hang on to and preserve, they have to use this limited monopoly they have. There is a human rights responsibility on pharmaceutical companies to ensure that they take certain reasonable measures to enhance access.

### **Keren Bright**

Professor Paul Hunt of the Law School at Essex University. He served for 6 years as UN Special Rapporteur on the right to the highest attainable standard of health.

But these issues are not simple – they're complicated. For instance, what about key medicines that are no longer protected by patents? Jon Pender of GlaxoSmithKline

### **Jon Pender**

The WHO has a list of three hundred and twenty five essential medicines that it says any basic national formulary should have to provide basic level of health care and of those three hundred and twenty five medicines, all but about six or seven have no intellectual property associated with them at all. No patents, no copyright, no trademarks, and yet the WHO says that a third of the world's population has no access to those medicines and in Africa and parts of Asia that grows to two thirds. So clearly the issue is around... just poverty driven, lack of health care infrastructure, lack of health care workers etc and nothing to do with intellectual property.

**Keren Bright**

So this suggests there are many other obstacles to getting medicines to women such as Lemlem Gessese.

**Paul Hunt**

I accept that there are other obstacles not all of which can be addressed by pharmaceutical companies. I mean, for instance, in many countries in the world there are collapsing health systems. There aren't distribution channels. One obstacle in some countries is corruption. There is the allegation that diversion or leakage is a problem. Some countries receive drugs at low prices and then, lo and behold, those drugs then leak back to those countries that are in a different socio-economic group and have much higher prices.

**Keren Bright**

Yet there is plenty of evidence that medicines are only targeted at rich countries or at the urban elites in poor countries, that prices are set too high and there is not enough transparency about those prices and about the costs of developing the medicines. Some peoples' view is that it's the MECHANISM for rewarding companies that's wrong and this needs radical rethinking.

**Thomas Pogge**

Pharmaceutical companies are often vilified these days. People say that they are evil, they're thinking only about profits. I don't really share their view. I think that much of the fault lies with us; with the politicians and our citizens, namely that we incentivise pharmaceutical companies in such a way that they cannot make profit on serving the needs of poor populations. The Health Impact Fund would change that and I think would allow pharmaceutical companies to do well by doing good.

**Keren Bright**

One of several alternative mechanisms, the Health Impact Fund is the brainchild of Thomas Pogge, Leitner Professor of Philosophy and International Affairs at Yale University and Aidan Hollis, Associate Professor of Economics, at Calgary University. The Health Impact Fund would keep patents, but remove their monopoly. How would the Fund work in practice?

**Thomas Pogge**

Suppose a company has a vaccine that shows promise for malaria. What normally would happen is that the company would mark that product up, would say, let's say, we can produce it for twenty cents a dose but we're selling it for two dollars a dose and we have to mark it up like this in order to recover our research and development expenses. With the Health Impact Fund the company would market the product at twenty cents- at cost - and it would be rewarded on the basis of the Health Impact of the vaccination campaign. So we would use existing rates of prevalence in the various countries of malaria as our baseline and we would observe how the introduction of this vaccination programme would bring that rate of prevalence down and we would then pay the company on the basis of reduced mortality and morbidity attributable to their vaccination campaign.

**Keren Bright**

And why should pharmaceutical companies be attracted by this?

**Thomas Pogge**

For example because they have a product that is essentially indicated for poor populations and therefore could not make much money on a mark up patent **track**. Those are the diseases, so called neglected diseases, that the patent system has left out like malaria, tuberculosis, Schistosomiasis, dengue fever, Buruli ulcer and so on.

**Dr Mohga Kamal Yanni**

It is an interesting idea but it's actually full of holes in the sense that it's still keeps the patent system totally intact. It also relies totally on drug companies' will to enter into this but doesn't give them the incentives.

**Jon Pender**

I think being paid by results as a concept is absolutely fine but how do you measure the impact that a new intervention has had when it's being added to lots of other interventions, is I think the real challenge. I was thinking around the example of the malaria vaccine where bed nets are being widely distributed, there's indoor residual spraying, you've got vector control initiatives, so if you add a malaria vaccine to that how do you differentiate the impact that that has had over all those existing interventions?

**Keren Bright**

Many campaign instead to make use of existing mechanisms – like voluntary licensing. That is permission to make a similar medicine. For pharmaceutical companies to give more voluntary licences to the so called generic companies.

### **Dr Mohga Kamal Yanni**

Generic companies are companies that produce equivalent or copies of new drugs. So the good generic companies would produce a drug same quality, it's the same drug basically but they save on two things. They save on the cost of initial research because the drug is already there so they don't do that bit, but also they have their own ways of saving in production and a lot of these companies are in India and Thailand and Brazil so, for example, the price of antiretroviral where you need three medicines to be taken at the same time for treating HIV. It used to be ten thousand dollars per patient per year. When Indian generics started making the medicines and came to the market it was like a price war actually to get the price down and eventually now you can have this cocktail of drugs for less than a hundred dollars per person per year, so a huge difference.

### **Keren Bright**

Patent pools are another method to widen access to medicines. They are seen as a potentially cheaper and faster way of developing medicines for neglected diseases. They are also another means for generic companies to license patents.

### **Dr Mohga Kamal Yanni**

It's like a one stop shop. So remember that every medicine doesn't have just one patent, it can have many, many, into hundreds even. So a patent pool is a way where all the companies put their patent in this pool, as it were, and then generic companies that want to produce these cocktails can go to this pool and get the patent without having to go round every company, every research institution, and produce the medicines and sell it at very cheap price and meantime they will pay a royalty to the companies that have the patent. So it's a win win situation.

### **Jon Pender**

What change we have seen over the last ten years and certainly, within GSK, accelerated in the last couple of years, is a willingness to pursue different business models and to recognise that a one size fits all approach is no longer appropriate. So that's why in particular for R&D we're pursuing an open innovation strategy. We've put eight hundred of our patents and patent applications into a new pool for open innovation. We've also put our knowledge and know-how into that pool because that's what researchers said they really needed to have access to. They needed to be able to ask us 'have you tried this? What happened when you did? How did you get over the stability problem?' This isn't designed to be a commercial opportunity for GSK at all so any products that are developed out of this pool, based on our intellectual properties, for the least developed countries will be on a royalty free basis.

**Keren Bright**

But if there's no gain at all for the pharmaceutical company, surely it's not sustainable?

**Jon Pender**

Well you're absolutely right to say that it doesn't overcome the fundamental issues of lack of financing and lack of incentives for R&D, so absolutely this isn't the only answer.

**Paul Hunt**

But pharmaceutical companies need to take more steps than they presently take to enhance access. They've got to engage in public/private partnerships, voluntary commercial licences. There might be a role for compulsory licences in some cases. Donation programmes will have a role too. Critically differential pricing between countries and within countries has to be undertaken. There are many things that pharmaceutical companies can do more robustly and more widely than they are doing at the moment.

**Keren Bright**

So what can leverage pharmaceutical companies to do better as regards widening access to medicines? The United Nations? Professor Paul Hunt.

**Paul Hunt**

In 2008 I tabled my Human Rights guidelines for pharmaceutical companies in relation to access to medicines. I tabled them with the UN General Assembly and I know that the pharmaceutical companies did not like the length of the guidelines – there are 47 guidelines. We had to be specific. For example, part of what the guidelines talk about is greater transparency in relation to lobbying or advocacy or promotional activities of pharmaceutical companies; who are they giving money to? on what conditions? for how long? and so forth. I think that's one area on which the pharmaceutical companies were somewhat unhappy.

**Jon Pender**

I think most companies, a lot of the policies which they pursue are very much aligned with the guidelines that the Special Rapporteur developed. However, there is a fundamental issue that underpins those guidelines and that is there is some sort of legal obligation on the industry to undertake access to medicines issues. That is something we don't accept.

## **Keren Bright**

By contrast, what has seemed to generated a positive response from the world's top twenty pharmaceutical companies is that Access to Medicines Index. It's an informal and independent audit carried out by the Access to Medicines Foundation.

## **Jon Pender**

I think there has been a real sense of companies wanting to be seen to be doing better and I think what is very satisfying from the coverage the Index has got is that it has focused on... accentuated a positive. It has focussed on those countries that have done better, it hasn't just concentrated on the laggards and I think that is very, very helpful.

## **Keren Bright**

It may look like we're stuck trying to soften the harsh effects of the patent system to make access fairer. But in some countries, notably Cuba, it is the state and not the pharmaceutical companies that decides which diseases to invest in and it is the state that owns the patents in any medicines developed. Andres Cadenas, an innovation economist at the University in Bremen, grew up in Cuba.

## **Andres Cadenas**

From the beginning they Cuban health ideology has been based on the idea that health is a right for all and a responsibility for the state and in that sense it is a responsibility for the state to guarantee funding for neglected diseases. For example, two vaccines that were developed for the National Centre of Scientific Investigation in Cuba, one was vaccine against Cholera and the other one was vaccine against pertussi. They were conceived to fill a necessity in other developing countries. Cuba has been really successfully by eliminating neglected diseases which are common in the rest of the developing world.

## **Keren Bright**

State direction and ownership works for Cuba – but other states will pursue those solutions most suitable for them. So what of the future? The issues introduced in this programme show the complexity around inequality of access to medicines. Improvements to access can be made using a variety of mechanisms and business models. Replacement of the current patent system is highly unlikely – but Dr Mohga Kamal Yanni points a way forward.



**Dr Mohga Kamal Yanni**

We don't want pharmaceutical companies to suddenly turn to be a charity but what we want them to do is take access to medicine as part of their business strategy. So starting from the beginning; you're going to make a drug, how is that drug going to be useful to people in developing countries?' and from there you move into 'how can I make it useful? How can I market it in a useful way? What do I do to make the price suitable for these countries?' To make it part of the business, at the moment, even with the counties that are doing better than the others, it's still at the margins. It's an afterthought and that's why the solution for it is afterthought solutions'

**Keren Bright**

Our guiding principle must of course continue to be the advancement of the right to the highest attainable standard of health and the reduction in the disparity of access to medicines and treatment as described by Vanessa and Lemlem Gessese.

If you have found the issues explored in this programme interesting, you may like to find out about a master's module at The Open University called 'Business, human rights law and corporate social responsibility', code WU822.

