

HOUSE OF LORDS
MINUTES OF EVIDENCE
TAKEN BEFORE
AD HOC COMMITTEE ON INTERGOVERNMENTAL ORGANISATIONS
CONTROLLING THE GLOBAL SPREAD OF INFECTIOUS DISEASES

MONDAY 21 APRIL 2008

UK Mission, Louis Casai 58, 1211 Contrin Geneva, Switzerland

DR JORGE BERMUDEZ and DR PHILIPPE DUNETON

Evidence heard in Public

Questions 662 - 707

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Present

Avebury, L.
Desai, L.
Howarth of Newport, L.
Jay of Ewelme, L.
Soley, L. (Chairman)
Whitaker, B.

Memorandum submitted by UNITAID

Examination of Witnesses

Witnesses: **Dr Jorge Bermudez**, Executive Secretary, and **Dr Philippe Duneton**, Adviser to Executive Secretary, UNITAID, examined.

Q662 Chairman: Thank you very much for coming and for the evidence you have already given. We have about one hour. You will have an opportunity to see the transcript, because the events of today are being recorded, and you will have the chance to correct any factual inaccuracies or anything you would like to clarify. If you feel you would like to send us any further information, if at the end you feel you have not dealt with everything, please do. Perhaps I could start by asking you to introduce yourself. I understand you are the Executive Secretary of UNITAID, but perhaps you would give us a little introduction as to what your job is and then we will go into questions.

Dr Bermudez: Thank you, my Lord Chairman. About myself or UNITAID?

Q663 Chairman: About yourself in relation to UNITAID.

Dr Bermudez: I think you have all the information we have given you on UNITAID.

Q664 Chairman: Your role in UNITAID.

Dr Bermudez: I will leave you two advance copies of the report of 2007. That is our first report. We just finished it for our Board two weeks ago in Brazil. These are advance copies, it is being printed. It is a very good overview of what we have done during the last year.

Q665 Chairman: Thank you.

Dr Bermudez: My name is Jorge Bermudez. Originally I was a medical doctor with a Masters in Science in tropical diseases and a PhD in public health. I come from Brazil. I have worked almost all my life in the national health system of Brazil, the Ministry of Health, at the province and state levels. I directed the National School of Public Health in Brazil. In 2004 I moved to Washington as a Unit Chief for essential medicines, vaccines and health technologies for the regions of the Americas. I worked for almost three years in Washington, responsible for Latin America and the Caribbean regarding medicines, vaccines and technologies. As you are aware, UNITAID was launched in September 2006, initially by five founding countries - Brazil, Chile, France, Norway and the UK. After UNITAID was launched, a hosting agreement was decided with the World Health Organisation and all posts have been filled by the World Health Organisation criteria. I applied for the post of Executive Secretary to UNITAID and was selected and came to office in July 2007, almost one year after it was created. From July 2007 I have been responsible for the day-to-day activities. I lead a team of 16 professionals from 11 or 12 nationalities. We are committed to all the by-laws and principles that were founded with UNITAID and have been developed and approved during all the Board meetings. As to our governance structure, we have an Executive Board composed of 11 members. Those are; the five founding countries, a representative from the African Union and a representative of the Asiatic countries, (currently from Korea), a representative from NGOs, communities living with the diseases, the private foundations (currently the Gates Foundation) and the World Health Organisation. That has met seven times up until now and our last meeting was two weeks ago in Brazil, for the first time outside

Geneva. All of the decisions of UNITAID are taken by that Board, by all its members, of course instructed and prepared by the Secretariat, and then it is up to us to implement all the actions that UNITAID has developed during the last year and a half.

Q666 Chairman: Thank you very much, that is a very comprehensive summary. One of the things that struck me about UNITAID was that it is quite an unusual organisation in the way that it was born, if I can say that, and it is also a “coalition of the willing”. I understand you have a few more country members now. How does that affect the way you work? Is it actually an advantage to have a coalition of the willing? Or do you feel it would be better if many more countries of the world were represented on it and there may be limitations to that structure? Is that right or not?

Dr Bermudez: I do not think there are limitations, because one of the initial ideas of UNITAID was not to overlap with what is ongoing, to have an additional value and select specific niches that were not being addressed to really make a difference. On the other hand, it is very important for us to have predictable, long-term --- *Dr Duneton .arrives at this point.*

Q667 Chairman: Welcome! We have done the introduction, Dr Duneton. Please complete your answer, Dr Bermudez.

Dr Bermudez: The basic ideas were additionality, not overlapping, specific niches to be addressed - and, of course, having predictable, long-term sustainable funds in order to comply with our main objectives, namely, to impact market dynamics, to extend the availability of products (because we only work with products), lower prices in markets, therefore stabilising the markets, and adding quality to the products they were using. In that sense, with eight countries up to this date, we have developed a model similar to what was proposed by UNITAID as a tax on airline tickets, so that will be a permanent tax that is predictable, or a multi-year commitment, as some countries (the UK and Spain) have already placed for

several years. That brings us stable financing that does not depend on the willingness of the governments to address other organisations as they have to negotiate every year. As this is predictable, we can negotiate long-term agreements with manufacturers, we can stabilise the market as we have forecasts for several years and, therefore, it is attractive for manufacturers. I do not think we are a coalition of the willing as you say but, let us say, committed countries with stable mechanisms that will ensure predictability. We do not work in the areas that others are working in, we work in complementarity with them - the Global Fund, WHO, UNICEF or any other organisations. Let me just introduce Philippe Duneton, our Deputy Executive Secretary. He comes from France and he may be the only one who has been there since the beginning of the creation of UNITAID working on the proposals and is now the Deputy Executive Secretary.

Q668 Chairman: You are very welcome. I understand you had a tiny problem getting here. Just to say to you that these events are recorded and you will have an opportunity to look at the transcript before it is made public. Just to finish off that question, in a sense you have a sort of programming function and a financing function. But how do you exercise oversight into how that is done to make sure that what happens on the ground is what you want to happen, if you like, making sure that your delivery is what you believe it ought to be?

Dr Bermudez: To continue with my comments on the last question, as we work in specific niches and only with products, all of our activities are dedicated to ensure products. We do not work in other areas, we let our partners work there. We do not work alone, we work with well-recognised partners that have field offices, country offices, implementing agencies or even procurement agencies, or other types of actors that will ensure within the country that the products that are funded by us - the products are funded by us, not the strengthening of the health system or the procurement and supply management system in the countries – arrive, and that is conducted by our partners. We work in other key performance indicators. We

have four main objectives: to ensure the availability of products; to ensure an adequate price of products; quality of products; and delivery of products. For each one of those objectives we have developed indicators, and in each one of our programmes we have analysed all the four indicators to see if we are impacting on price, quality, availability and lead time. Last year we presented to our Board in December an analysis of HIV/AIDS - related programmes and now we are doing that with TB and Malaria. In all of our programmes we have reached adequate results based on the indicators that we have developed. Another issue I mentioned previously was that we only work in specific niches that are not addressed. For example, in HIV/AIDS everybody knows that the Global Fund has a very big programme on first-line antiretrovirals, so we do not know work with first-line antiretrovirals. We discussed that with the Global Fund and are funding second-line antiretrovirals for resistance to first-line and paediatric antiretrovirals. There was a gap in paediatric antiretrovirals because nobody was addressing that. In TB we are working with multi-drug resistant TB and the Global Fund says UNITAID is responsible for that, and we work with them and other organisations addressing multi-drug resistance. In Malaria we are working with the Artemisium compound, ACTs, that is the future for Malaria, and we are also engaged in a multi-taskforce that is dealing with the so-called Affordable Medicines Facility for Malaria. That puts together WHO, UNICEF, UNAIDS, UNITAID, the Global Fund and the World Bank, working to make sure that we will have products available worldwide for Malaria. We will address quality, the pricing of these medicines, children's medicines. Thanks to our long-term financing, we have introduced new products in the market because it is attractive to manufacturers. In TB and paediatric antiretrovirals we have new fixed-dose combinations that are much more pleasant for the child to take and much more quality-assured because they have been pre-qualified by the World Health Organisation scheme.

Q669 Chairman: The production of a good quality drug is one thing, the delivery of that drug to the individual who needs it, given the problems in some developing nations, is another. How would you have confidence that you are delivering that sort of quality to the individual who needs the drug?

Dr Bermudez: Quality for the manufacturer and the WHO is clear, because we are addressing that and our new product will be delivered to the market. How you make sure those products will be delivered to the people who need those products and that they are of quality, that is why we work in partnership with other organisations that work in that field, and we ensure that by means of agreements with the Ministries of Health of other countries. We do not work out of the health system. All of our programmes have agreements with the Ministries of Health in the countries that are receiving the products to make sure those medicines will flow through the health system and be adequately received, stored and distributed through the supply system. We have Partners who have field officers who will monitor that for us as well.

Chairman: Thank you. I think Lord Avebury would like to ask about your relationship with the World Health Organisation.

Q670 Lord Avebury: Just before I come on to that, could I ask whether you are planning to expand the number of contributors. I think it went up from an initial five to 27. Are other States coming on board? Is the airline tax being extended to further carriers beyond those who signed up originally?

Dr Bermudez: I will answer that in two stages. We began with five countries supporting that, and now some African and other countries have said that they want to support that and have come on board, either by the air tax or by implementing in other ways or by multi-year stable financing. We have been discussing this, and other countries have said they want to, but they want to have more details about how they can implement that. Some countries are

working on that. A new idea that we have had approved by our Board and in a conference call last week is a proposal - and you have probably heard that our chair is a former Minister of Foreign Affairs of France, the Under-Secretary of Ban Ki-Moon, the United Nations' General Secretary - for innovative mechanisms for financing development. He has been committed and talking about the possibility of a voluntary solidarity contribution that would be managed throughout the global data systems in the world. We are aware that 65 per cent of air tickets that are issued worldwide are issued through three main global data systems - Galileo, Amadeus and Sabre - that generate internet-based transactions. The three CEOs of those agencies have agreed to work closely with UNITAID to see the possibility of implementing a voluntary solidarity contribution, as some other actors have done in hotel bookings. If correctly addressed, in the most pessimistic situation that would add about \$300 million per year up to \$1.8 billion that could be reached if we implement a voluntary solidarity contribution. That is an idea that is being rapidly developed and it has been announced since our chair, Philippe Douste-Blazy, was named Under-Secretary of the UN.

Q671 Lord Avebury: It sounds like a terrific idea, except that it conflicts a little bit with what UNICEF are already doing on airline tickets, does it not? They have a voluntary contribution that people are asked to pay when they get on board the aircraft and there is a leaflet on the seat which invites the passenger to pay something towards UNICEF. If you are going to require this voluntary contribution to be made at the time of booking, then a lot of people are going to say, "Why should I pay twice?"

Dr Bermudez: Then they do not pay twice.

Q672 Lord Avebury: Otherwise it is a tremendous idea. Could I then come on to your relationship with WHO and ask why it is that WHO could not have undertaken the functions that you have described? Was it simply because there was a limitation in their constitution?

If that was the case, why would it not have been better to alter their constitution so that they could have done the work that you are now doing?

Dr Bermudez: First of all, WHO is a UN technical unit and we do not consider ourselves a technical unit. We rely on WHO technical expertise. We are an operational unit. WHO has offices in other countries and other regions, it works mostly with capacity building, strengthening health systems, and with guidelines and documents, workshops, seminars, Standard Treatment Guidelines, and we adopt those for our work. WHO is not a procurement agency or a funder of products. They have a model list of potential medicines, they have a pre-qualification scheme that works within the UN system, but they do not work with procurement and do not have the lead time that is needed to rapidly disburse and attend to the country's needs. We think that WHO have their rule and we respect their rule, we do not do technical activities but we rely on WHO's technical actions and their solid background. They do not do procurement unless it is necessary for small issues. They do not act in the areas that we are acting in.

Q673 Baroness Whitaker: Could I just ask, is it that WHO would advise you on which drugs you ought to go for? Is that how they would come in? Or are there other ways?

Dr Bermudez: WHO has Standard Treatment Guidelines for paediatric treatment for HIV/AIDS, for TB, for Malaria, and we use those as guidelines. We see what is addressed by other Partners and what would be the need for second-line antiretrovirals, for paediatric antiretrovirals, according to WHO guidelines, because they have standard guidelines for pregnant women, for adults, for children, and we make sure we do not overlap with that. For procurement and delivery we use other Partners and we go to the countries and the countries' Ministers of Health, sign agreements to incorporate that into their health systems and we fund it.

Q674 Baroness Whitaker: Does it suit you how you are lodged within the intergovernmental machinery? Are there different roles or different powers that you would like to have? Or, if WHO were differently constituted, would that help you at all?

Dr Bermudez: It is very clear to us what are the different roles of the different organisations and it makes it easy for us to work with WHO, UNAIDS, UNICEF, the Global Fund, because we have different architectures, different business models, different financial activities and complement each other. We are very much aware and have discussions with them. One of our major partners is the Global Fund. More than a year ago the Global Fund's Board and UNITAID's Board requested that we work together to see what roadmap we could develop jointly so that we do not overlap and what would be the added value that we could have in the strengthening and scaling up of access to products for the three diseases, because the Global Fund also works with the three diseases. We have found our role, their role, the complementarity and we work together with them.

Q675 Baroness Whitaker: So structurally you are where you want to be?

Dr Bermudez: Yes, structurally we are a lean secretariat hosted by the WHO, so we are on the health side and that is important for us because we work with a health perspective in delivering products. We are gaining experience with their expertise in the three diseases. We interact very strongly, almost every day, with the Department for HIV/AIDS, the Department for TB, Department for Malaria, the Partnerships they have, as Roll Back Malaria and Stop TB, and the Medicines Department and the health system. They do their work and we are an added-value to their work.

Q676 Baroness Whitaker: Thank you. Could I finally ask, do you give any priority to local manufacture and accreditation, because that would have eventual health benefits in that

it would increase growth, it would increase capacity? For instance, I think Artemisium grows in Tanzania; I do not know whether Novartis cultivates it there.

Dr Bermudez: We are supportive of that, but we do not work alone on that because other organisations have very specific roles, for example UNIDP, the United Nations Industrial Development Organisation. We have worked with them to see how they can strengthen local manufacture in areas that we will have a forecast of and that will justify having local manufacturing. Your example is very clear where you talk of Artemisium in Africa in Malaria, where we are working on that. Also, pre-qualification is not for us, the World Health Organisation will pre-qualify manufacturers, examine their dosage, make sure that they comply with good manufacturing procedures, and we can fund the products. But we will only fund pre-qualified products to make sure that we have quality. In that sense, WHO is supporting manufacturers for them to reach this status of pre-qualified drugs and manufacturing.

Q677 Lord Desai: There are a lot of overlapping agencies around, and one of the questions is; can you simplify. In your case there is the Global Drug Facility, and I wonder; is there a rationale for you guys getting together and going into the Global Fund? Or is there no advantage to that sort of streamlining?

Dr Bermudez: Initially, the Global Drug Facility only works with TB. In TB we are Partners with the Global Drug Facility because in some countries they have Regional Offices. We established a partnership with them, and for first-line TB, for multi-drug resistant TB, we work with the Global Drug Facility. The Global Fund has a completely different architecture. When we worked with antiretrovirals, when we were assessing the products that we deliver, one of the issues we compared was the lead time that we had to deliver products. Let us say we sign an agreement. How much time does it take between the signing of the agreement and for the product to be delivered in the country? We compared that with PEPFAR, the USA

programme for AIDS relief and the Global Fund, and our lead time takes weeks: PEPFAR takes months, sometimes a year; and the Global Fund takes years. They are not intended to be a procurement agency. Their strategies are based on rounds that they discuss with the country and in that sense the country applies for grants from the Global Fund, and in those grants they have the strengthening of the health system, human resources, products and diagnostics. From the signing of that to the end takes one, two, sometimes three years. They are completely different architectures. We consider that we have a specific role in funding products, shortening lead times, supporting WHO pre-qualification and ensuring the scaling-up and a rapid response. We had two emergencies last year because of a stock-out of malarial medicines in Liberia and Burundi in Africa. We discussed this with UNICEF and WHO, and in four weeks the medicines were arriving in the country, so we prevented stock-outs of medicines. I can assure you that the Global Fund does not work with emergencies because they have long-term financing for the countries.

Q678 Chairman: You do not see yourself as an organisation that mainly focuses on an emergency, you see it as more general than that?

Dr Bermudez: Yes.

Q679 Chairman: I suppose this is what we are struggling with a bit. We have had people say to us that there are so many actors in this whole international field that it is difficult to get coordination without overlapping and, therefore, wasting resources. There is another argument that says that all of these organisations are doing a good job and all we have got to do is get the coordination right. Those are the two arguments. How would you evaluate those arguments, if you like? Do you think you are quite relaxed about the number of organisations? Is the coordination good or bad? Or is there room for rationalisation of the number of organisations?

Dr Bermudez: First of all, the other organisations are there and we will not discuss whether they should be there or not. We have a very specific additional role. One of the issues that needs to be addressed, and we have discussed this with all the other organisations, is how to coordinate the in-country actions, because in-country there are several organisations acting with different Partners, different delivery mechanisms, different quality standards, so it is very difficult for countries to receive sometimes. We have discussed the supply systems in several African countries and are amazed when we see the numbers of organisations that fund, that deliver, that work with human resource building in the countries, and sometimes they do not speak to each another, there are four, five, six or ten organisations working in a country. When we see countries in crisis, that is worse because we have international aid flowing and everybody is eager to help and in an emergency that is very clear. We are very specific in that we only fund products that others are not funding. We do not work with emergencies, but we have because, when we realise the only way to avoid new cases of resistance is to avoid stock-outs, we work with those emergencies just to cover certain gaps in partnership with other organisations when we realise that nobody is funding that. Our main mission is to fund products, let us say commodities, for diagnostics, for treatment, where they are not currently funded by other organisations. We always work with the idea of additionality and not overlapping.

Q680 Lord Desai: My next question is related. You mentioned running out of drugs in one or two situations and also the strategic rotating stockpiles. Can you say a little bit more about that so we understand.

Dr Bermudez: When we were discussing with Stop TB and the Global Drug Facility, there was a problem last year that 18 countries in Africa had been granted Global Fund grants but they would be receiving funds for those grants in two or three years. Most of them were being covered by the Global Drug Facility and Stop TB but were running the risk of stock-out

because of the gap between the end of the financing they had for those medicines and the time they needed to receive the Global Fund funds to be able to continue. We took to our Board a strategic decision: “This is an emergency, it is not our current business but we have been requested by WHO, UNICEF, the Global Drug Facility and the Global Fund to see if we can work together on a rotating stockpile of medicines - a transitional programme, because we will not maintain that for the rest of the years - to avoid stock-outs and the emergence of resistance and people who will not receive their medicines”. The Board understood that it was an exceptional measure that should be approved and supported, but not a normal activity that we would undertake. That was helped by creating a stockpile that was managed between the countries as necessary and was administered by the Global Drug Facility.

Q681 Lord Jay of Ewelme: I would just like to go back one stage, because I want to be quite certain I understand what you do. I understand that, if there is a drug which exists and has received pre-qualification and is acceptable, then it is comparatively straightforward; you would identify a need, you would talk to UNICEF or whoever, you would order it and deliver it as soon as you could to the deliverer, as it were. That seems clear. Where I am slightly less clear is that you said earlier on you only purchase drugs for which there is WHO pre-qualification. But do you act rather like advance market commitments in the sense that, because people know you are there and you may put in a big order for something, that encourages research, encourages development, encourages companies to go for pre-qualification, so you are acting as a spur to the research and development of drugs as well as purchasing them?

Dr Bermudez: Yes.

Q682 Lord Jay of Ewelme: Could you just give an example of a drug that was not quite there yet until you came along, if you see what I mean?

Dr Bermudez: I will mention two points. First of all, when we began to discuss the paediatric ARV programme, there were 40,000 children on treatment in the world. We discussed this with the Clinton Foundation and decided to introduce 100,000 new treatments per year during three years, so in 2007 we introduced 100,000 and then we had 140,000; in 2008 we will have another 100,000, so 240,000; and in 2009 it will be 340,000. The needs that are estimated in the world are around 500,000 to 600,000, so we will be responsible for most of the paediatric treatments in the world. That led an Indian manufacturer, Cipla ---

Q683 Lord Jay of Ewelme: At that stage there was no drug?

Dr Bermudez: There were adult drugs that were used by children.

Q684 Lord Jay of Ewelme: There were no drugs specifically-designed for children?

Dr Bermudez: No. There was no fixed-dose combination, three drugs in one pill for the children.

Q685 Lord Jay of Ewelme: So you were identifying the need with the Clinton Foundation for a product that did not exist?

Dr Bermudez: Yes. The three products existed individually but nobody had put them together. Cipla did that for the first time. That was pre-approved by the US Food and Drug Administration and the WHO recognised it, so now the product is being used not only by us and the Clinton Foundation but by other organisations in other African countries. When we support the WHO pre-qualification scheme, WHO in its report of 2007 on pre-qualification stated, "Thanks to UNITAID funding, 31 new products were pre-qualified in 2007". We have 31 new products that would not have existed pre-qualified for the three diseases. Most of them are for HIV/AIDS because the market for HIV/AIDS is larger. We are trying to move

faster to Malaria and TB as well. Last year we had 31 new products pre-qualified by WHO related to UNITAID funding.

Q686 Lord Jay of Ewelme: You are value-added, therefore? First of all, you have got the money because the money is coming from the 27 countries?

Dr Bermudez: Yes.

Q687 Lord Jay of Ewelme: Secondly, you are developing relationships with a whole series of manufacturers, is that right? What you bring to the Clinton Foundation or UNICEF or some other donor is the ability to go and talk straight away to the manufacturer and say, “This is what we want and what we would like you to develop”.

Dr Bermudez: This is what will happen in the next two or three years.

Q688 Chairman: If you would like to come in on this - I see you nodding, Dr Duneton - please do.

Dr Duneton: No, thank you, I do not have much to say on that. We had the chance and the opportunity to demonstrate what was initially in our constitution. The example chosen by Jorge about the FDC/ARV paediatrics is also the same in TB because it was a question put by GDF. When we started discussions with GDF, they had a project they had had for three years to have a specific combination for paediatrics, but they did not have any money to do that. In one year we provided the first combination for TB in partnership with GDF. By the way, it was a surprise that we had a good quality product and with the same money we could treat four times more children than we expected. It has a market dynamic impact. The important word is “dynamic,” because when you change to move something it has some positive consequences.

Lord Jay of Ewelme: If I could just make a comment. It seems to me that the speed with which this has got off the ground and is operating, given the speed at which UN organisations normally operate, is actually pretty remarkable. It was only three years ago that this was thought up and you are now sitting here saying to us, “We have already had these discussions, we have ordered the drugs and they have been used”. It is quite remarkable.

Q689 Lord Howarth of Newport: You mentioned that among your ambitions is to focus on the procurement of second-line drugs. These are fantastically expensive - \$4,500 per TB treatment, and in the case of ARVs something like ten to 20 times the cost of first-line treatments. While I am extremely pleased that the UK has made a commitment to support you for 20 years, you also talk in your evidence of a “dearth of predictable long-term funding”. More and more patients are going to need these second-line drugs and that may bring the unit cost down, but how confident are you that you are going to be able to see this through and afford the cost of this programme?

Dr Bermudez: Your issue is relevant because it really is very expensive as we increase. When we look back to the past and see where HIV/AIDS was 20 years ago, nobody expected us to be able to fund HIV/AIDS. Everybody said it would be unfundable because of the cost, but the cost has been brought down for first-line medicines and they cannot go lower, because they are at the lowest price and we have more than one million people in treatment with first-line. On second-line drugs, as Philippe said, we treat three children now where before we treated one. It is not so easy in TB, because the market is more difficult and active principle manufacturers are not so well-known. We know less of the market on the TB drugs than we know of the ARV or HIV/AIDS products. We are analysing all the global market manufacturers on active principles of the final products to see how we can link one with the other to make sure that we will have stable manufacturing throughout the years. If prices are not brought down, we will reach a point where we will not be able to fund more. In TB we

also have an additional problem in that for second-line TB we have to invest in diagnostics, because in many cases we do not know where they are and the countries do not know. If we want to advance, one of the things we have discovered is we need to invest in diagnosis. We will not be able to fund MDR-TB alone but we are one of the major funders. We are treating 5,000 MDR-TB patients and have committed to a project with a global representative of the Green Light Committee to expand as much as we can. I agree with you that it is a very difficult problem, and it is unpredictable as to whether we can fund in the long-term, but we will do our best to continue and lower prices now.

Q690 Lord Howarth of Newport: Your business model has already, through the use of your purchasing power, demonstrably been able to bring down the costs of certain drugs, but where the drugs do not exist there is another set of problems, is there not? You were speaking of TB, and I think you mentioned in your written evidence that paediatric TB is a neglected field. Presumably, that is a consequence of market failure, whereby the drug companies are interested in producing new products to meet the needs of the affluent West but not of the developing world - you cite appalling statistics: less developed countries 84 per cent of the world's population, 93 per cent of disease, 11 per cent of global health expenditure. This is market failure on a colossal scale. Do you see your organisation having the purchasing power and the firepower in the marketplace to be able to commission new research so that new products are produced to meet the needs of the developing world that are not being financed on the present market model?

Dr Bermudez: Yes. In partnership, of course. As we have mentioned, we do not work alone and we will not be able to fund research.

Q691 Lord Howarth of Newport: No, it is very expensive.

Dr Bermudez: But we have other Partners we are working with. For example, I can mention TDR, Tropical Diseases Research, in WHO and the Drugs for Neglected Diseases Initiative and various trans-national companies and foundations that are dealing with research and working with, let us say, DNDI, (the Drugs for Neglected Diseases Initiative) in developing new products for neglected diseases, and I think TB would be considered in that. At this moment we are not committed to fund research because others are doing that.

Q692 Lord Howarth of Newport: Is that because the costs of it are simply too great for you to contemplate? Or because it is a task that others will perform?

Dr Bermudez: It is both. It would need too much funding and others are dealing with it. What we can do in partnership with those is to try to forecast what the future market will be. We had the introduction of paediatric TB drugs after we began to work with Stop TB. That will be a predictable market if we foresee that in the years to come we will have an increasing demand and it may be attractive for industry. We may have the support of industry from other organisations, such as those I mentioned a few moments ago, and you need to work with other organisations that may support manufacturing.

Q693 Lord Howarth of Newport: Meanwhile, to overcome the problems that there are with intellectual property rights you are focusing on your scheme for patent pools. Will you tell us more about that and expand on that proposal - how you see that working and who would be your Partners in terms of getting things to happen?

Dr Bermudez: It is a very incipient activity, or non-activity, but it is a discussion within UNITAID. We and the French Government received a request from NGOs, especially *Médicins Sans Frontières*, to try to work on the concept of patent pools and how that exists in other areas - in aviation, music - but has never been applied to medicines in the pharmaceutical setting. We were asked if UNITAID would be able to move ahead on

establishing potential patent pools that would enhance success for medicines, especially fixed-dose combinations. We opened a tender, commissioned a report with IPDS from McGill University in Canada and that delivered a first report. I just want to go back some years and say we strongly think this is a continuation, initially of the UK CIPR (Commission on Intellectual Property Rights) that delivered a report four or five years ago. Then the Commission on Intellectual Property Rights, Innovation and Public Health in WHO delivered a second report, the CIPIH, and now the Intergovernmental Working Group continues to discuss how to move. These are three sequential movements in three products that have been brought forward and we are following very closely. Based on McGill University's report that says that patent pools are feasible, legally and administratively - of course, it is a sensitive area because it deals with intellectual property and the right to health - it would be feasible and we need to move to see what would be geographic coverage, coverage of medicines, which products, how to deal with voluntary licensing in a patent pool and, if it is an issue, to deal with compulsory licensing in a patent pool, how would that deal with other stakeholders. Based on that report we had an initial meeting of a small group of people, which included people from academia, NGOs - not from governments, because we did not put the countries in because the countries have to approve or not of what we are doing. We moved to try to figure out what are the steps that would be necessary and submitted that to our Board two weeks ago. Our Board said they see a great advantage and they asked us to continue. We will still be working on what will be the potential of a patent pool, starting on the principle that initially it will be a voluntary licensing patent pool. It is for countries to apply compulsory licence requests from a patent pool, but it is not an idea that will begin as a compulsory licensing patent pool, because we need to bring the pharmaceutical industry and innovative engineers in to discuss that with us and we will address it then - what will be the governance structure for that, the constituency for that and the initial needs and steps to be taken. That will remain as

an issue to be discussed with our Board, and our Board will take the final decision, not at the next Board meeting but in two or three Board meetings' time. We understand that is an issue that will continue with some months of discussions because it is not an easy discussion. On the other hand, UNITAID has been called as a concerned entity in the Intergovernmental Working Group, so we are following that closely.

Q694 Lord Howarth of Newport: Do you anticipate that you will have the endorsement and practical collaboration that you will need from some of the other organisations that obviously have an interest - the World Trade Organisation, WIPO and also the World Health Organisation? Are they likely to be on board?

Dr Bermudez: Yes. We invited all of them to the discussion and it included the World Health Organisation and WIPO. The WTO was not able to come, but they will be on board and we will continue to discuss this with them, of course.

Q695 Chairman: Why was it not possible for the World Trade Organisation to come?

Dr Bermudez: It was just one meeting.

Q696 Chairman: You have no problems in discussions with the WTO?

Dr Bermudez: No.

Q697 Chairman: You would not do that through government, you would do it directly as UNITAID?

Dr Bermudez: As UNITAID, we want to have an independent group that will have a proposal that can be taken to our Board. We have followed very closely the IGWG discussions and sometimes there are some impasses and tense situations. We do not want that to be brought to a group that is discussing how to move. Of course, when we sit with the governments, they have their points of view, and we understand that clearly, but we do not

want that to be an intergovernmental discussion between two governments, we want to have impartial information to take to our Board, and then our Board will discuss that. Our Board has the UK, Norway, Brazil, Chile, France, the Asian countries, African Union, NGOs and WHO to discuss that.

Q698 Chairman: You obviously have discussions with the pharmaceutical companies about pricing directly and so on for things you might buy, but what about their overall policy. Would you discuss that with them or not?

Dr Bermudez: For a patent pool?

Q699 Chairman: Yes.

Dr Bermudez: We will discuss with them but we want to have a clearer idea of what are the different options before having that discussion with the pharmaceutical industry.

Q700 Chairman: Their argument would be that they have got to have sufficient money to do the research, and the other side of the argument is that it is too expensive to deliver the drugs even though you have brought new money to it, if you like?

Dr Bermudez: We will have that discussion with them at any stage that we are able to move.

Q701 Lord Avebury: When we were talking a few minutes ago about the very high cost of second-line drugs, I was looking at your written evidence where you said that the cost of the second-line MDR-TB treatments could be brought down by 20 per cent during the currency of the commitment of the \$20.8 million from 2007-11. Is that based on contractual discussions with the manufacturers? Is there an advance market commitment which you are discussing with them? Or would that be a useful tool to help bring the price down?

Dr Bermudez: Those are initial discussions based on the current manufacturers' price of the active principle ingredients and the possibilities of working like we have done with ARVs, for

example, with the cost-plus methodology. All the costs need to be known and some companies are open to that, but others are not. Based on that assumption, we would have an estimate of what the impact would be, but we have not discussed that thoroughly with the manufacturers.

Q702 Lord Avebury: Are you thinking about an advance market commitment?

Dr Bermudez: Not in the sense that it is being used with vaccines currently. That is an open idea that we need to follow very closely. It has been used in vaccines, but vaccines and medicines are completely different models because of the time of development of vaccines, the strains that are necessary, the specificity of manufacturing. In pharmaceuticals you have a much shorter cycle, a faster return to manufacturers and it is a completely different approach. We understand an advance market commitment as is being done for vaccines will not be discussed relating to medicines now. It may be a possibility, but we will not say at this stage we will do something like that.

Q703 Chairman: You have enormous experience and it is clearly very focused on what you are doing, but it must have given you a very good picture of what is happening in the world of disease and treatment and the international organisations. If you step back from your own organisation, put that to one side for a moment, and if you were looking at this whole area, WHO and all the many organisations, and I asked you what are the problem areas that are not being covered and what are the real pluses of it, what would your answer be?

Dr Bermudez: One issue is that phrase that has been raised several times here - medicines are in the north and patients are in the south, the imbalance between what has been manufactured between offer and demand, what has been manufactured, delivered and what is the potential in years to come. We have introduced a different view in some of the areas where we have worked. We have seen the price of second-line ARVs being brought down, so they are three

times less than was initially thought. We need to have an overall multi-stakeholder initiative that understands that access to medicines are a part of health and have to be delivered. Some countries are able to pay and some countries are not able to pay. We are funding and our constitution is very clear, that 85 per cent of our resources has to go to low income countries (and we think that is correct) and only 15 per cent to lower-middle income countries or medium-middle income countries. Many of the low income countries are not able to pay, so we need to know how to expand the availability of resources to treat those diseases as the global emergencies that they are.

Dr Duneton: I think it is obvious, and all the organisations recognise the need to find a better way to strengthen the capacity at country level. I will give an example. Of course we want to be focused on the product; but, having said that, we need to think what the product will be used for. We have certain limitations because we do not want any overlap. In the case of diagnostics, it is not only a question of devices and commodities, it is a question that is more about the service. It is just an idea for now, but we have discussed that with Partners and industry and they have shown some interest, saying we could organise the support. By the way, we are already doing that through the Clinton Foundation for diagnostics for paediatrics, not only paying for products but for the results. That is exactly the same way that we consider this in the northern countries. We are not paying for a PCR device or a part of this, because that does not work. In fact, in a lot of countries in the south it does not work because you can have the device but, if you do not have the human resource to use that kind of device properly, you have nothing and you have paid for nothing. I have tried to look from outside the organisation but, in a way, it is a question not only for us but also for our Partners. It is useful to think in that way of something a little bit different and saying we have that impact on the product. But, if we are paying for a service, it could be something for us to think about again, not only us but with Partners and industry.

Q704 Chairman: What sort of organisation would that be that would do that?

Dr Duneton: Just as an example, the Clinton Foundation. With the experience of others we have started to think about that, and that is the way it works now. We have had initial discussions with UNICEF on that, with major industries like Roche or Abbott, not trying to set something but to see the idea.

Q705 Chairman: The shape in a way?

Dr Duneton: Exactly. It was a recommendation issued by the assessment that we have paid for that, when we assess the diagnostic part of TB, maybe there is a need to think in that direction. It is something on how to move in the next three years maybe.

Q706 Chairman: If you get any more thoughts on that in the reasonably near future - we have to report in July - please let us know, because it sounds quite interesting. Any further questions? Is there anything you have left out at all that you want to raise or you feel we have missed? Is there anything at all you would like to say?

Dr Bermudez: No, thank you very much.

Q707 Chairman: Thank you very much.

Dr Bermudez: We have to support more than 80 countries and I think we are moving forward in the right direction.

Chairman: That sounds very good. Thank you.