



Call for evidence- Access to Medicines in the Developing World

APPG enquiry: *Achieving Universal Access – The Treatment Timebomb Part II*

Deadline for Submissions is Wednesday 19th March 2014, 9am

Guidance for Submissions

- The submission should be in Word format;
- It should be clearly stated who the submission is from, i.e. whether from yourself in a personal capacity or sent on behalf of an organisation;
- It should comprise a single document attachment to the email;
- It should begin with a summary in bullet point form;
- It should have numbered paragraphs;
- It should be no longer than 3000 words;
- Please only answer the questions which you feel are relevant to you, do not feel you have to answer all of the questions;
- Please use the question headings and numbers to organise your response.

Written evidence may be referenced in the final report. If you wish for your evidence to be anonymous please make this clear. Submissions should be emailed to the group's Policy Advisor, Susie Pelly at: Susie.pelly@parliament.uk. If you have any queries about the report or require further information please contact Susie at the email address above, or by calling 020 72195670.

Background to the Inquiry

In 2009 the All Party Parliamentary Group on HIV and AIDS conducted an inquiry on the supply of affordable anti-retroviral medicines (ARVS), which concluded that the high price of second and third line drugs for HIV was a major barrier to access to HIV treatment. The report was successful in mobilising political support for the Medicines Patent Pool, and in highlighting the "Treatment time bomb" which exists as people in developing countries switch from first line HIV treatment to more expensive second and third line drugs.

Since then there have been significant developments in anti-retroviral treatment, most notably with the results of the HPTN 052 trial which concluded that HIV treatment can be highly effective in preventing the transmission of the disease. There are also a number of new ARV drugs appearing in the market which will likely represent the future of HIV treatment and access to them will become central in the coming years. In 2011 World leaders agreed to a target at the UN of putting 15 million people on treatment by 2015. However in 2013 the World Health

For more information please contact Susie Pelly Policy Advisor to the APPG on HIV and AIDS: susie.pelly@parliament.uk 02072195670



Call to Evidence for Access To Medicines Inquiry 2014

Organisation changed its guidelines to start ARV treatment at an earlier stage in the illness when a person's CD4 count reaches 500cells/mm³. This means that an estimated 26 million people should be eligible for ARV treatment, making the 2011 UN target of reaching 15 million people less ambitious than previously thought. Another major development since 2009 is the establishment of the Medicines Patent Pool.

The broader context of this inquiry should also be taken into consideration. Universal Health Coverage has become an increasing global priority and commitment. This inquiry will try to incorporate this by looking at the importance of medicines in achieving that goal. According to the WHO 2010 Report 'Health Systems Financing: The Path to Universal Coverage', medicines account for 20–30% of global health spending, slightly more in low- and middle-income countries, and, therefore, constitute a major part of the budget of whoever is paying for the health services of a health system. For that reason, this inquiry will focus particularly on the issue of access to medicines and diagnostics for HIV and more specifically what measures can be taken to reduce their price to enable more efficient health systems. The APPG would therefore like to go back to the recommendations of the report, assess what progress has been made since 2009 with regards to international access to HIV medicines and diagnostics and to highlight any emerging challenges.

While we recognise that price is not be the only limiting factor, and that other factors such as supply chain management, strength of health systems and cultural and social issues may also impact upon the ability of countries and suppliers to ensure that HIV medications are available to all of those who need them, this inquiry will focus primarily on the issue of price of medicines - because it can be the single most important barrier even when all other conditions are in place. Furthermore, it is an issue which governments and the private sector in the West have the power to address to make a huge difference to the lives of the poorest, as demonstrated by the spectacular gains made in access to ARVS over the past twenty years.

Given the large number of recommendations in the original report, the questions in this call to evidence are intended to be broad and to address the bigger picture issues highlighted by the Treatment Timebomb. They are not restrictive. You are welcome to comment on other areas relating to the recommendations if you feel that is appropriate.

Process: Launch written call for evidence: Early Feb

Potential Fact Finding Trip – (April)

Round Table oral evidence session: May (depending on recess dates)

Launch: July

Questions

Using the recommendations from the Treatment Time Bomb as a basis please focus your submission on the questions below. You need not provide an answer to all the questions, only those for which you feel you have evidence or expertise. Please number the paragraphs and use the questions as headings.

Question 1

For more information please contact Susie Pelly Policy Advisor to the APPG on HIV and AIDS: susie.pelly@parliament.uk 02072195670



The following milestones were highlighted in the Treatment Timebomb report as clear signs of progress in achieving universal access to medicines:

“Affordable quality first and second line drugs; access to products for co-infections; more paediatric treatment options; affordable diagnostics to ensure adults and children are diagnosed in time to prevent permanent damage to their immune systems; affordable and effective prevention of mother to child medicines.”

- i) To what extent have the milestones been met?
- ii) If they have not been met what factors are impeding their progress and what steps can be taken to achieve them?
- iii) Taking into particular consideration the new WHO guidelines, the latest developments in treatment as prevention and the new ARVs entering the market, what new milestones do you believe should be set?
- iv) Over the next 5 years what do you believe will be the biggest threats to the security of access to medicines for patients living with HIV? (e.g. price of new ARVs, co-morbidities, ageing, diagnostics, drug resistance, etc)
- v) What assessment has been made of the financial sustainability of achieving universal access to medicines for HIV and what measures need to be taken to ensure that there are sufficient funds to finance it?
- vi) Which recommendations of the 2009 report are still valid and need to be emphasised/implemented?

Question 2

In the Treatment Timebomb different access schemes for pharmaceutical companies were assessed for their viability including voluntary licences, tiered pricing, the use of TRIPS flexibilities and the idea of a medicines patent pool. Since the report was written in 2009:

- i) Please describe what in your opinion have been the most successful access schemes and provide clear evidence of their successes.
- ii) Are the access schemes currently used by pharmaceutical companies sufficient to achieve universal access to medicines, if not why not?
- iii) What other access schemes not currently in use do you believe could be effective in achieving universal access to medicines?
- iv) There has been clear progress in 2013 by the Medicines Patent Pool in attracting pharmaceutical companies to undertake public health oriented licenses? How do we ensure that this continues? How important will MPP licenses be for new ARVs (e.g. cobicistat, dolutegravir, TAF, elvitegravir)?
- v) Given the increasing number of countries graduating from low income to middle income status, what measures need to be taken to ensure the poorest in those countries continue to have access to medicines and are able to benefit from access interventions largely focused on low income countries?

Question 3

Treatment Timebomb addressed failures in the R & D model and argued that patents alone are not acting as a strong enough incentive for typically developing world issues such as lack of

For more information please contact Susie Pelly Policy Advisor to the APPG on HIV and AIDS: susie.pelly@parliament.uk 02072195670



research and development into paediatric HIV medicines and lack of research into the interaction of ARVS with common co-infections such as TB and Hep C.

- i) What in your view can be done to address these failures of the current R & D Model in relation to HIV and associated co-infections, please use the subheadings below:
 - a) 'Reforming the current system'
 - b) 'Alternative models of R & D with particular focus on HIV and the interplay with key co-infections'
- ii) How should these reforms or alternative models be paid for?
- iii) To what extent can R & D policies address the high prices of HIV medicines that have not yet come to market?
- iv) Since Treatment Timebomb was released in 2009, what policies to address these failings have been successful and why?

Question 4

Treatment Timebomb recommended that the World Intellectual Property Organisation (WIPO) be held accountable to its development agenda in helping countries to use their TRIPS flexibilities to protect public health:

- i) To what extent is WIPO fulfilling this agenda?
- ii) In your view, how successful have the TRIPS flexibilities been in bringing down the price of medicines?
- iii) What can other key institutions, including the WTO and WHO do to ensure TRIPS flexibilities are preserved or used to protect public health? Have other institutions fulfilled their mandate?
- iv) Since the publication of the report, have signed FTAs or FTAs under negotiation had or will have a harmful impact on public health? What more can be done to ensure that trade agreements are not prejudicial to public health?

Question 5

Another recommendation in Treatment Timebomb was that drug registration processes are streamlined to enable medicines to reach the market more quickly and efficiently and that the WHO Treatment guidelines and the WHO Model list of Essential medicines are also adopted:

- i) To what extent have drug registration processes been streamlined?
- ii) To what extent have the WHO Treatment Guidelines and Essential Medicines List been adopted and implemented?
- iii) Has the time from regulatory approval of new ARVs by originators to their availability in developing countries from quality assured generic manufacturers been shortened?
- iv) How effective has the WHO Prequalification function been at assuring the quality of medicines for developing countries and improving regulatory capacity in those countries?

Question 6

For more information please contact Susie Pelly Policy Advisor to the APPG on HIV and AIDS: susie.pelly@parliament.uk 02072195670



Call to Evidence for Access To Medicines Inquiry 2014

- i) What leadership needs to be taken by the UK Government in particular, key multilateral organisations and the private sector to achieve universal access to medicines for HIV?
- ii) To what extent has multi-sector collaboration taken place, what are the obstacles to it and what could be achieved if overcome?

Question 7

- i) What should access to medicines look like in the Post 2015 framework?
- ii) What should research and development look like in the Post 2015 framework?



Annex

Recommendations from “The Treatment Timebomb” Report

Recommendations from the introduction

1. HIV needs to be understood as both an emergency for those without treatment and as chronic condition for those with it. Developed and developing country governments and donors therefore need to make long term plans, beyond 2015 for funding and deploying an adequate response.
2. Key organisations purchasing HIV medicines, such as the Global Fund, UNITAID and PEPFAR, require assurances from donors that financial commitments will be secured for the longer term.
3. Advocates of universal access to HIV treatment, care and support need to agree on a common message to drive and maintain progress beyond 2015.
4. Treatment is needed to save lives, but prevention is the only way to manage the epidemic in the long term. Each infection averted saves years of treatment costs. Developing country governments, international NGOs, donors and others should work together urgently to develop best practice recommendations on prevention: treatment spending ratios.
5. UNAIDS should collect data on the extent of the use of CD4 tests, and donors should stand ready to fund the roll-out of a cheap, easy to use CD4 test as it becomes available. This could dramatically improve survival rates for people with HIV.

Recommendations from Section 2

1. Donors and developing countries should invest in the use of more effective PMTCT (prevention of mother-to-child transmission) drugs, as this will save money in the future and save lives.
2. Urgent action needs to be taken to reduce the cost of the WHO recommended first line alternative to the basic d4t+3TC+NVP combination, to enable the treatment of those who cannot tolerate Stavudine.
3. Urgent action needs to be taken to reduce the cost of second line medicines, which are a matter of life and death to those who need them.
4. There is a need for research into the costs of treating common opportunistic infections so that realistic financial allocations can be made when planning HIV programmes.

Recommendations Section 3

1. There should be an independent analysis of the relative costs and benefits of different types of pharmaceutical access programmes. DFID would be well-placed to conduct this.
2. Pharmaceutical companies should open up their access programmes to independent audit to increase confidence in them.
3. Buyers of ARVs should continue to work together, with the support of the WHO, to provide reliable forecasts to the pharmaceutical industry of the volumes they intend to procure.

Recommendations on enabling generic production (section 4)

1. WIPO should be held accountable to its development agenda, and asked to demonstrate examples of supporting developing countries to use their TRIPS flexibilities to protect public health.
2. DFID should consider supporting developing countries in their use of TRIPS flexibilities, both by funding technical advice and at a diplomatic and advocacy level, by encouraging cooperation from pharmaceutical companies.
3. Private partnerships between originator companies and generics can be profitable for all involved and improve access. Gilead's partnerships in India are an example of this. This approach should be encouraged.
4. Regional entities such as the East African Community (EAC), and its southern African equivalent the Southern African Development Community (SADC), that allow for cooperation among a group of countries, should work together to negotiate flexibilities and share lessons.

For more information please contact Susie Pelly Policy Advisor to the APPG on HIV and AIDS: susie.pelly@parliament.uk 02072195670



5. The UK Government should use its influence at the EC, particularly given the EC Trade Commissioner post is held by the British, to halt the adoption of TRIPS+ clauses in trade agreements that limit the ability of developing country governments to protect public health.
6. Customs authorities in EU states should desist from detaining life-saving drugs in their ports when these shipments are destined for third countries where no patent is infringed.
7. The UK Government should use its influence at the EU, to require a review of EU customs regulations that allow such detentions, and assess their impact on access to medicines.

Recommendations from section 4B

1. UNITAID, and the big funders of drugs purchasing, such as the Global Fund for AIDS, TB and Malaria, have a good chance of breaking the 'chicken and egg' volume/price deadlock, if they indicate they are willing to fund the more expensive drugs, such as Tenofovir.
2. The WHO also has an important role to play in ending the dead-lock by promoting its recommendations more clearly and updating them regularly.
3. Developing countries will be more willing to change their preferred drugs if they can be shown to be appropriate to them. Funding for clinical trials is needed to produce data showing the relative efficacy of various treatment options in a resource-limited context and where there is a shortage of health care workers to help deliver them.
4. Donors could consider setting up an international facility based on the UK's National Institute for Clinical Excellence (NICE). The International Institute of Clinical Excellence would help countries to decide which drugs should be prioritised to meet their national health goals.
5. Efforts to harmonise the regulation of drugs will improve access but must be negotiated with sensitivity, to ensure willingness to participate. It would be helpful if such efforts were championed by a developing country or regional organisation. This could speed up the delivery of newer, better drugs to market and save money.
6. PEPFAR should end its policy of requiring FDA approval as well as WHO approval of the medicines it supplies.
7. Key donors such as the Global Fund, PEPFAR and UNITAID should continue to work to clarify and coordinate their tender processes and lead times and engage with all the relevant companies that comprise the pharmaceutical industry to provide improved global demand forecasting.

Recommendations on encouraging R & D (Section 5)

1. The private sector has excellent skills and experience in translating early academic stage research into usable products. They are more likely to engage in this expensive, risky process, if there are incentives for them to do so. Proposals to stimulate R&D need to ensure adequate financial incentives.
2. There is an urgent need for improved capacity for clinical trials in developing countries. Donors not currently funding such work should consider doing so, in collaboration with organisations such as the Medical Research Council, academic institutions and private companies.
3. Pharmaceutical companies and other patent holders should sign up to the UNITAID patent pool to enable new fixed dose combinations (FDCs) and paediatric versions of
4. HIV drugs, in return for a fair royalty on their patents.
5. HIV funders should consider investing money in late stage research, a process that the Clinton HIV/AIDS Initiative has begun to facilitate, on the basis that such research has already proved its worth and that there is scope for further gains.
6. DFID, in communication with its counterparts from other donor countries and with UNITAID, should look into the workability of a prize fund for key missing medicines and diagnostics.
7. In a global economic downturn there will be a temptation to divest from ambitious research projects such as an AIDS Vaccine, but this should be resisted because long-term stability is essential to make gains from investments thus far, and because new prevention technologies have the potential to revolutionise our response to HIV and minimise the epidemic.