Country perceptions for implementation of the new multi-drug resistant TB (MDR-TB) medicines.

Report

A survey conducted among the 27 high MDR-TB burden countries

March – July 2015

Stop TB Partnership in collaboration with Medecins Sans Frontieres (MSF)

Stop TB Partnership

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Contents

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Background:

Tuberculosis (TB) is a deadly communicable disease with an estimated 9.0 million people who developed TB in 2013[1]. Of this, 3.5% of new cases and 20.5% of re-treatment cases are globally estimated to have multi drug-resistant tuberculosis[2]. These proportion translates to 480,000 people having developed MDR-TB in 2013.These rates of MDR-TB are particularly high in Eastern Europe and Central Asia regions. Further an estimate of 9.0% of patients with MDR-TB had extensively drug resistant TB (XDR-TB)[3].

Following concerted efforts to strengthen laboratories and roll out of rapid test the detection of MDR-TB has increased over the years. Countries have also made progress in the delivery of MDR-TB treatment. Current treatment regimens lasts 20 months or more requiring daily administration of medicines that are more toxic, less effective and far more expensive than those used to treat drug-susceptible TB.

For the first time in over four decades there is progress in research and development of new medicines such as the discovery of Bedaquiline and Delamanid.

Bedaquiline (Sirturo) is a diarylquinolone anti-tuberculosis medicine discovered by Janssen Pharmaceuticals, approved by the U.S. Food and Drug Administration (FDA) on the 28th December, 2012[4] for the treatment of adults with multi-drug-resistant pulmonary tuberculosis for whom an effective treatment regimen is not available.

While reviewing the bedaquiline marketing application the down side is that in one of the phase 2 studies, there were more deaths among patients who had bedaquiline added to a background antimicrobial drug regimen than among those who had a placebo added to the same regimen despite clear evidence of its efficacy in clearing *Mycobacterium tuberculosis* from sputum. However, to consider the approval of bedaquiline, the FDA weighed the benefits of treatment with bedaquiline for patients with smear-positive MDR-TB for whom insufficient treatment options against the risks, including the observed mortality imbalance.

The WHO issued "interim policy guidance" for use of bedaquiline[5] in January 2013, which provides advice on its inclusion in the combination therapy of MDR-TB in accordance with the existing WHO guidelines for the Programmatic Management of Drug- resistant TB.

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[1] WHO Global TB report 2014 : http://www.who.int/tb/publications/global_report/gtbr14_executive_summary.pdf?ua=1

[2] Multidrug-resistant tuberculosis (MDR-TB) is a form of TB caused by bacteria that do not respond to, at least, isoniazid and rifampicin, the two most powerful, first-line (or standard) anti-TB drugs. http://www.who.int/mediacentre/factsheets/fs104/en/

[3] XDR-TB : Extensively drug-resistant tuberculosis XDR-TB is defined as resistance to at least isoniazid and rifampicin, and to any fluoroquinolone, and to any of the three second-line injectables (amikacin, capreomycin, and kanamycin) http://www.who.int/tb/challenges/mdr/tdrfaqs/en/

[4] FDA Approval of bedaquiline – the benefit-risk balance for drug-resistant tuberculosis http://www.accessdata.fda.gov/scripts/publications/search_result_record.cfm?id=50172

[5] WHO interim guidance on the use of bedaquiline in the treatment of MDR-TB: http://www.who.int/tb/challenges/mdr/bedaquiline/en/

The WHO recommendation for the inclusion of bedaquiline in the adult treatment regimen of MDR-TB is subject to the following five conditions being met:

1. Treatment is administered under closely monitored conditions, adhering to best practices in treatment delivery to enable optimal drug effectiveness and safety.
2. Proper patient inclusion.
3. Patient informed consent obtained.
4. Adherence to principles of designing a WHO-recommended MDR-TB regimen.
5. Pharmacovigilance and proper management of adverse drug reactions and prevention of drug–drug interactions.

Otsuka's **delamanid** (OPC-67683) is a new anti-tuberculosis medication indicated for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability. It was granted conditional approval by the European Medicine Agency in April 2014[6] and WHO interim guidance was issued on the use of delamanid in the treatment of MDR-TB in October 2014[7] that listed five conditions that must be in place if delamanid is used to treat adults with MDR-TB.

The five conditions on the use of delamanid, include:

1. Proper patient inclusion
2. Adherence to WHO recommendations when designing MDR-TB treatment regimens.
3. Effective treatment and monitoring
4. Pharmacovigilance and management of adverse events
5. Informed consent

A study published by The New England Journal of Medicine showed that delamanid plus a background regimen rendered more study subjects non-infectious after two months than placebo plus background regimen alone (53% increase in sputum culture conversion after two months)[89]. This finding suggests that delamanid could enhance treatment options for multidrug-resistant tuberculosis.

An international Phase III trial has been initiated in study subjects with MDR-TB, including those taking anti-retroviral medicines for co-existing HIV infection (estimated study completion date is May 2016)[10]. Information about this new medicine, therefore, remains limited, since study results only exist on the completed Phase II b trial and studies for safety and efficacy so far.

No guidance have been published so far on the use of the two medicines together. These two medicines offer great potential for improving MDR-TB treatment and providing options for treatment

[6] European Medicine A SUMMARY OF PRODUCT CHARACTERISTICS: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002552/WC500166232.pdf

[7] WHO interim guidance on the use of delamanid in the treatment of MDR-TB: http://www.who.int/tb/features_archive/delamanid/en/

[8] Delamanid for Multidrug-Resistant Pulmonary Tuberculosis: http://www.nejm.org/doi/full/10.1056/NEJMoa1112433

[9] The New England Journal of Medicine Publishes Efficacy Results of Otsuka's Delamanid for Multidrug-Resistant Tuberculosis: http://www.businesswire.com/news/home/20120606005698/en/England-Journal-Medicine-Publishes-Efficacy-Results-Otsukas

[10] Safety and Efficacy Trial of Delamanid for 6 Months in Patients With Multidrug Resistant Tuberculosis: http://clinicaltrials.gov/ct2/show/results/NCT01424670

of patients with extensively drug resistant TB (XDR-TB). However, we were yet to learn countries views and responses on the inclusion of these new medicines into their treatment regimens or policies.

The Stop TB Partnership collaborated with Medecins Sans Frontieres (MSF) to gather the views of national TB programmes from the 27 high MDR-TB burden countries to understand their point of view, barriers to use, intention of use or scale up on the use of the new MDR-TB medicines bedaquiline and delamanid.

Objective of the study :

- To assess information on the use or lack thereof of new anti-TB medicines, bedaquiline and delamanid in 27 high MDR-TB burden countries.
- To identify the potential barriers in the use or scale up of the use of the new medicines in countries

Methodology:

A survey questionnaire with closed ended questions was used to gather information from the target audience. Some of the questions had a provision for describing their choice response in the questionnaire. The questionnaire was implemented through a web based survey using 'survey monkey'[11] for responses in the period between the months of March – July 2015.

Questions pertaining to gathering information on countries knowledge of the new medicines, their registration, availability of a framework for "compassionate use[12]", or other mechanism allowing pre-approval access to unregistered medicines for patients with no other treatment options, were included. Also included are questions on the presence of a national policy on the medicines, a national plan to roll out the new medicines and budget availability. Multiple responses were allowed for the question on probable barriers preventing countries from using the medicines. The survey concludes with comfort level of using the new medicines and whether they would recommend their use.

Target Audience:

The National TB Program of 27 High MDR-TB Burden countries i.e. Armenia, Azerbaijan, Bangladesh, Belarus, Bulgaria, China, Democratic Republic Congo (DRC), Estonia, Ethiopia, Georgia, India, Indonesia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Myanmar, Nigeria, Pakistan, Philippines, Republic of Moldova, Russian Federation, South Africa, Tajikistan, Ukraine, Uzbekistan and Viet Nam [13].

National TB Programme Managers assisted by their staff, of the country responded to the questionnaire.

Results:

The survey was open from **March 2015** to **July 2015** and responses were received from 25 of the 27 targeted high MDR-TB burden countries. Despite repeated follow up, responses could not be obtained from two of the 27 countries i.e. China and Russian Federation during the survey period.

The below data is taken from 25 high MDR-TB burden countries.

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[11] Online survey https://www.surveymonkey.com/r/YDXVNFH

[12] Compassionate use is a treatment option that allows the use of an unauthorized medicine. Also called Expanded Access.

[13] 27 high MDR-TB burden countries , table 5.1 of the Global TB Report 2014 http://www.who.int/tb/publications/global_report/gtbr14_main_text.pdf?ua=1

Have countries heard about the new medicines bedaquiline and delamanid?

Of the 25 responses, 23 countries have heard of both bedaquiline and delamanid. One country had only heard of bedaquiline and another have not heard of either of the new medicines during the time of the survey (March – July 2015).

Are either of the medicines bedaquiline and delamanid registered (i.e. approved for use) in the country?

Bedaquiline is registered in 7 countries, is in the process of being registered in 6 and has not been registered in 12 countries. With regard to **delamanid,** it is registered in 3 countries, is in the process of registering in 3 and has not registered in 19 countries.

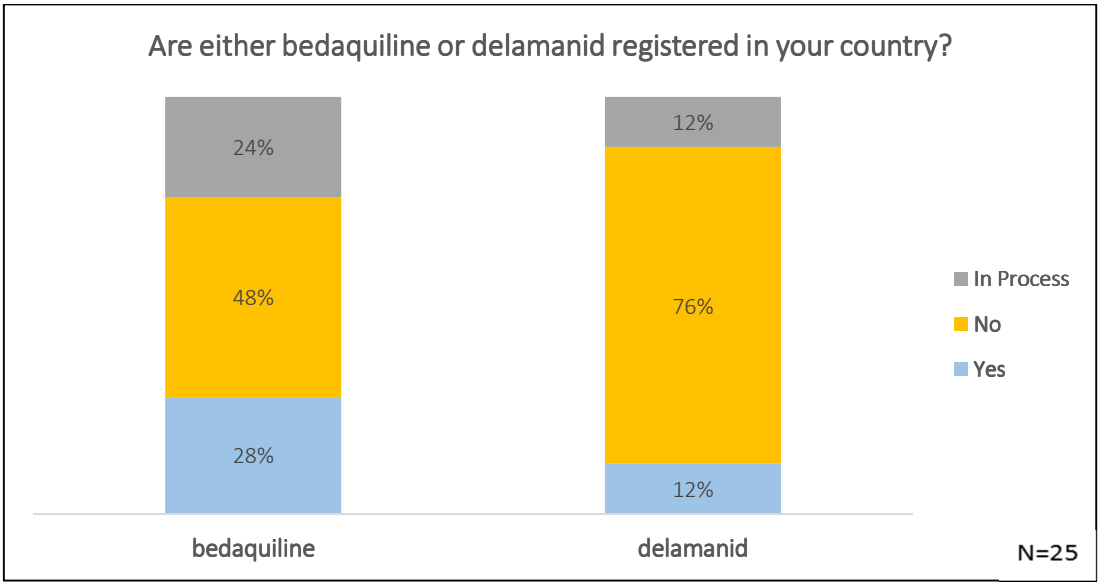

Figure 1: Registration of the new MDR-TB medicines in countries

Do countries have a framework for "compassionate use," or other mechanism allowing pre-approval access to unregistered medicines for patients with no other treatment options?

Of the 25 responses that was received 17 (68%) countries have a framework that allows pre-approval access to unregistered **bedaquiline** for patients with no other treatment options and 14 (56%) of countries for **delamanid**. There is no framework in 5 (20%) countries for bedaquiline and 7 (28%) for delamanid with 3 (12%) and 4(16%) respectively having no knowledge of the framework availability in the country.

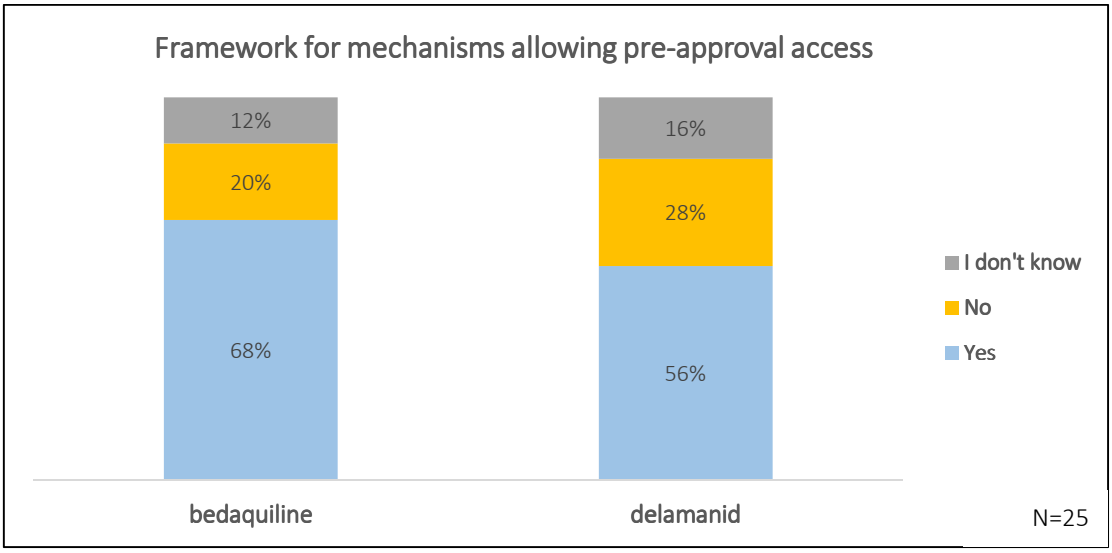

Figure 2: Presence of a framework for pre-approval access to the new medicines

A follow up question to countries that have a framework for pre-approval access to determine the number of patients who benefited from the new medicines.

The 17 countries with the framework on mechanisms allowing pre-approval access to **bedaquiline** have benefitted a total of **587 MDR-TB patients** and the 14 countries with the framework for **delamanid** have benefitted **50 MDR-TB patients**. Of the countries who have treated MDR-TB patients with the new medicines, South Africa have put 411 patients on bedaquiline as they have registered bedaquiline and also have a framework allowing pre-approval access to bedaquiline. Philippines has helped 40 MDR-TB patients on delamanid.

Do countries have a national policy on use of any of the new MDR-TB medicines?

There were 25 responses for bedaquiline and 23 responses for delamanid to this question. Only 6 of the 7 countries who have registered **bedaquiline** have a policy in place for its use, additionally 10 countries are in the process of making a policy for its use. The policies in each of 6 country were made in the time period below:

Policy on the use of bedaquiline	
Belarus	January 2015
Ethiopia	December 2014
Estonia	February 2015
South Africa	October 2013
Tajikistan	June 2014
Uzbekistan	December 2014

Policy on the use of delamanid	
Estonia	February 2015
Ethiopia	December 2014
South Africa	May 2015

Countries that are in the process of preparing a policy on the use of **bedaquiline** include Bulgaria, DR Congo, Georgia, India, Indonesia, Pakistan, Republic of Moldova, Tajikistan, Uzbekistan and Viet Nam.

With regard to policy on use of **delamanid** 3 of the countries have policies on its use with 3 countries in the process of policy making i.e. Georgia, Pakistan and the Republic of Moldova.

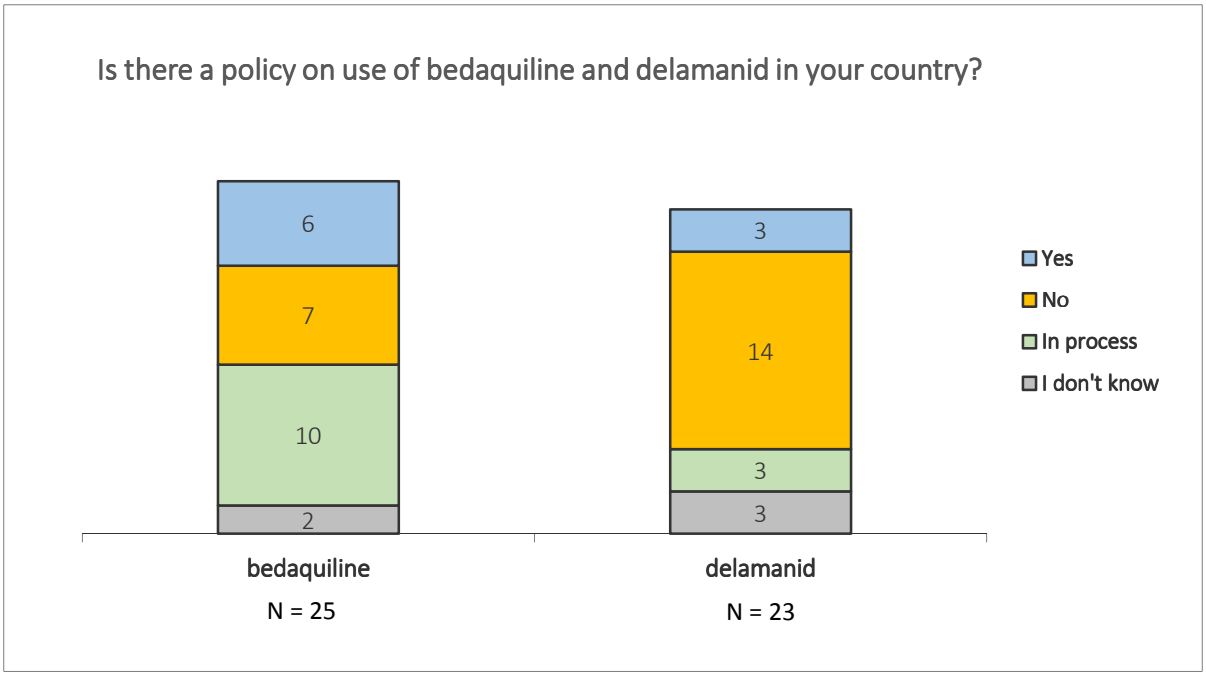

Figure 3: policy on use of the new MDR-TB medicines

For countries that do not have the policy on the use of the new MDR-TB medicines, were they planning on making a policy in 2015?

Responses were 18 for the question and the choices were; 6 countries plan on making policies for both bedaquiline and delamanid in **2015**, 8 countries plan only for bedaquiline and 4 countries with no immediate intentions. No country reported on plans to develop a policy for delamanid in **2015**.

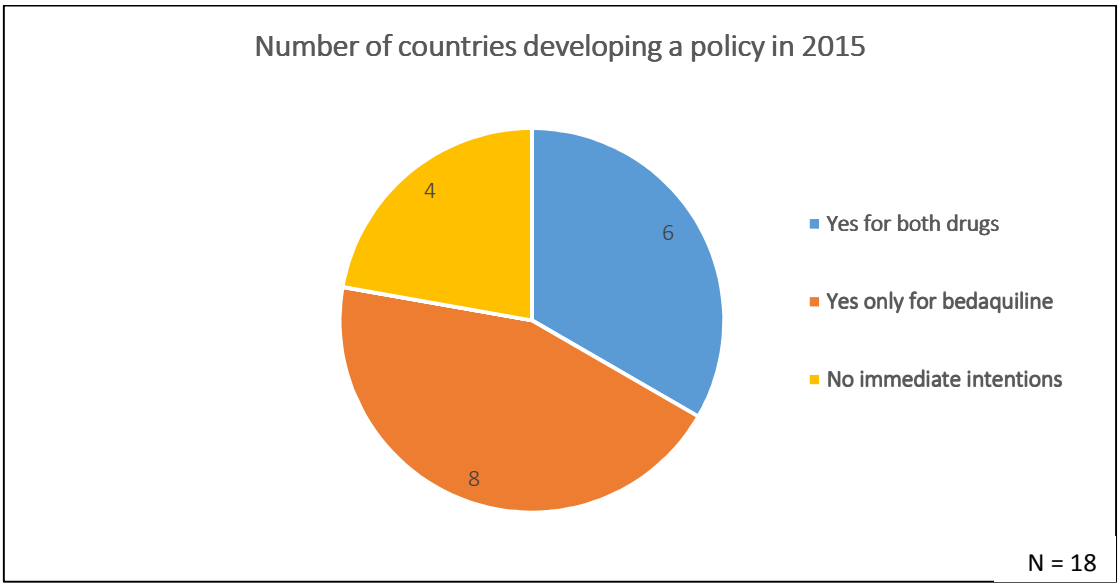

Figure 4: Countries developing a policy for the use for the new medicines in 2015.

Do countries have a national plan to roll out bedaquiline and / or delamanid in treatment regimens?

With regard to countries plan on roll out of the new medicines in treatment regimens, responses were received from 23 countries. 11 countries plan to roll out **bedaquiline** in their treatment regimens and 10 others will make bedaquiline available through the compassionate use or expanded access program with 2 countries not planning to roll out bedaquiline. The numbers for **delamanid** is much less. Only

22 countries responded to this question, with 7 countries planning on rolling out delamanid in treatment regimens and another 7 countries plan to make delamanid available through compassionate use or expanded access program.

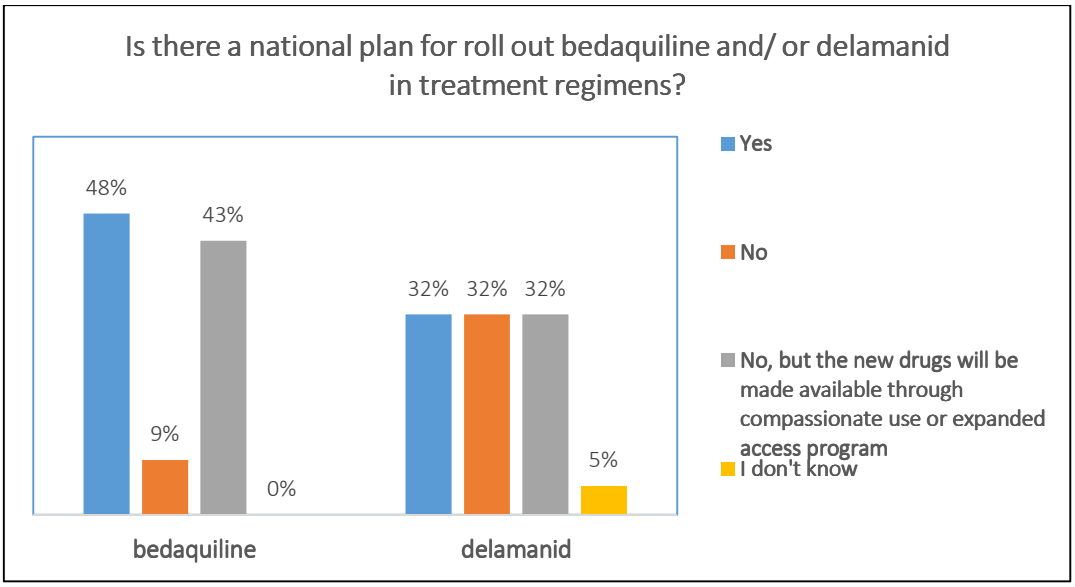

Figure 5: National plan for rolling out the new MDR-TB medicines in treatment regimens

About 9/11 (82%) of the countries with plan to roll out the use of bedaquiline and delamanid in treatment regimens have budgeted their inclusion in their national plans (Figure 6). The source of funding anticipated for rolling out the new medicines is about 84% from donors like USAID, Global Fund and only 16% have cited domestic funds. (Figure 7)

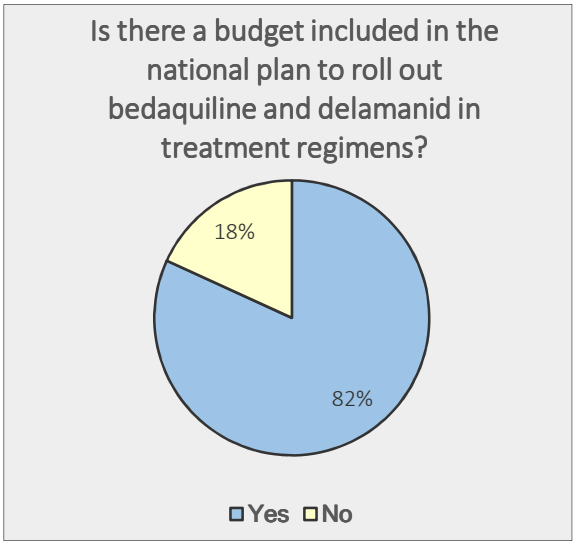

Figure 6: Budget for roll out in national plan

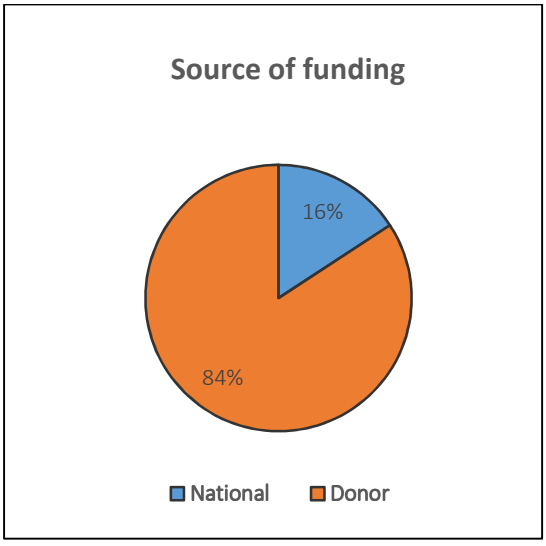

Figure 7: Source of funding

What are the barriers that prevent countries from the use of the new MDR-TB medicines?

A list of probable reasons was provided to the respondents to choose from. Respondents could choose more than one reason as applicable to the country context. The choices were:

i. Limited knowledge of the medicine

ii. Economic barriers, i.e. cost of the medicine and/or companion medicines
iii. Concerns about the side effects
iv. Practitioners not trained in their administration
v. The medicine and/or companion medicines not registered in country
vi. Challenges working with manufacturing companies
vii. No legislation for compassionate use or expanded access programmes

Barriers to the use of **bedaquiline** in countries**;** 52% states that bedaquiline is not registered in the country**,** followed by 43% concerns about the side effects and economic barriers i.e. cost of the medicine as barriers, 35% agree that limited knowledge and practitioners not trained in the administration of bedaquiline, 26% no legislation for compassionate use and least popular reasons being challenges working with the manufacturing companies and no country protocols available for use.

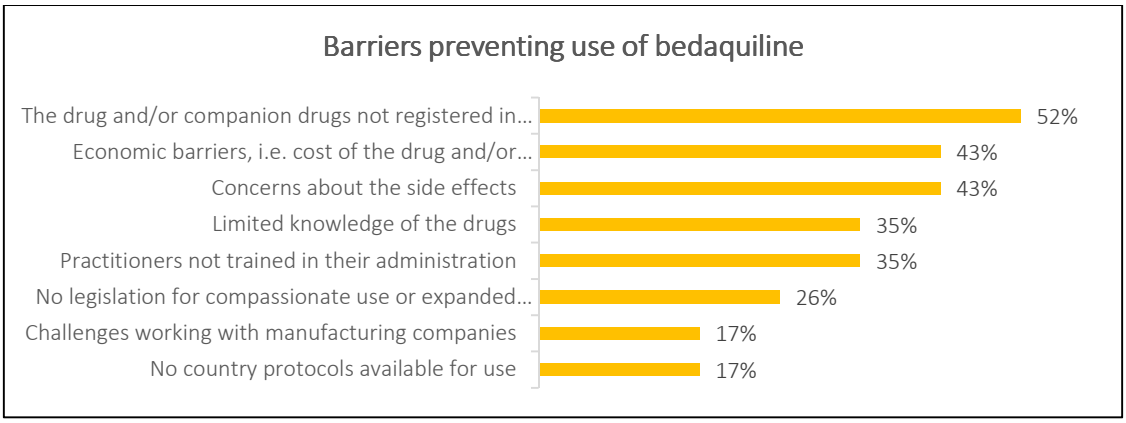

Figure 8: Barriers to the use of bedaquiline in countries

Barriers to the use of **delamanid** in countries**;** most selected reason of 52% of countries is that the delamanid is not registered in the country**,** followed by 48% of countries choosing the economic barriers i.e. cost of the medicine, 35% countries agree that limited knowledge of delamanid, practitioners not trained in the administration and concerns about the side effects comes as next reasons, 30% agree that the no legislation for compassionate use and the least popular choice was the challenge working with manufacturing companies.

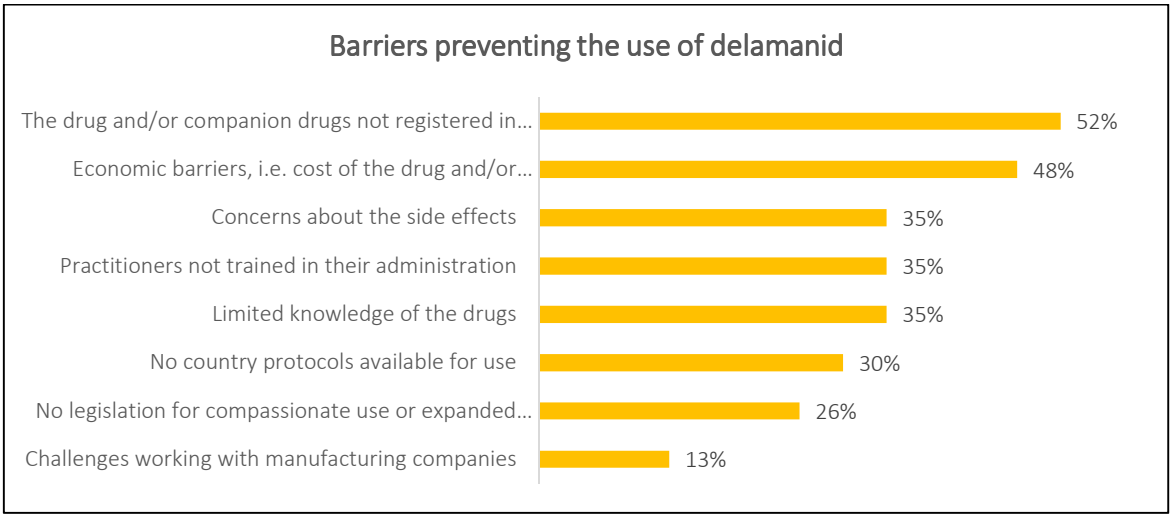

Figure 9: Barriers to the use of delamanid in countries

Other reasons of barriers for use of the medicines cited were:

- The programme intends to generate safety and efficacy data first on a limited number of patients carefully selected, review outcomes and then decide on scale up.
- Problems with introduction of the Global Fund Grant Project under New Funding Model.
- Only WHO guidelines on use of bedaquiline and delamanid available
- Budget & Supply for Bedaquiline
- Otsuka does not have an office in South Africa

Are countries comfortable on using the new MDR-TB medicines?

Countries are comfortable on using the new medicines with 17 countries comfortable on the use of bedaquiline and 15 countries comfortable using delamanid. A few countries are uncertain about the use of the new medicines i.e.7 countries for bedaquiline and 9 countries for delamanid. One country is not very comfortable in using them as they have not heard or used the new MDR-TB medicines.

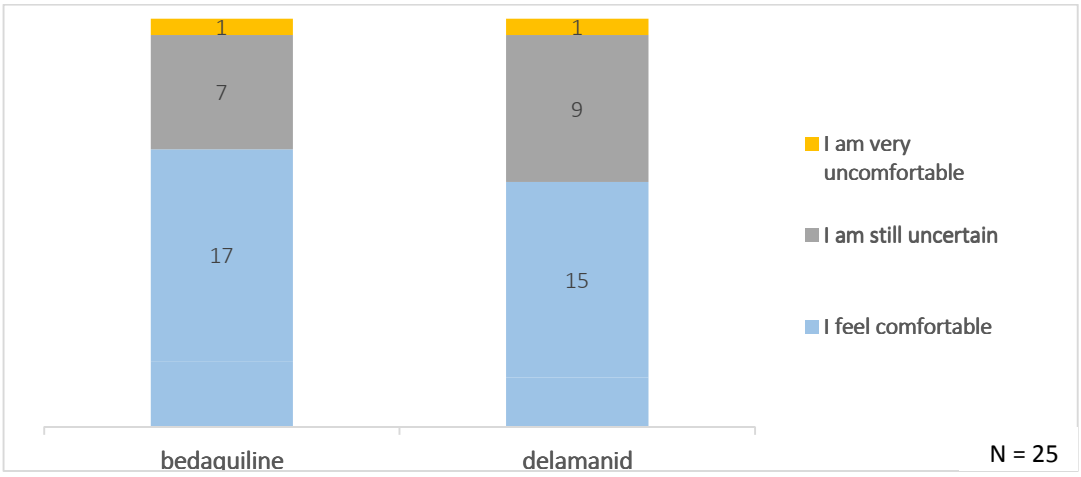

Figure 10: Countries comfort level on using the new MDR-TB medicines

Respondents were offered the opportunity to elaborate their choice of response on comfort level of using the new medicines. Responses are stated below verbatim:

I feel very comfortable using the medicines as we, the National Tuberculosis Programme have established the Bedaquiline clinical access programme providing bedaquiline to 211 patients between March 2013 and December 2014. We have since scaled up to a further 200 patients. We are in the process of establishing a delamanid access programme – South Africa

I feel comfortable on using bedaquiline because we have some XDR-TB to treat and we feel we need to do more – DR Congo

I feel comfortable on using both medicines as we have conditional approval in Estonia, both are on market, our country participated in trial with delamanid and bedaquiline and compassionate use program. M/XDR-TB patients have individual treatment schedules supervised by expert-consortium. Before new medicines were introduced, there were trainings to doctors and nurses – Estonia

I feel very comfortable on using both medicines as they are non-injectable second line medicines, and are breakthroughs in TB medicines. These two are essential to ensure cure for difficult to treat XDR-TB/Pre-XDR-TB cases for whom we do not have more options – Ethiopia

I feel comfortable on using both medicines as t*hese are the new anti-TB medicines the TB society and patients have been waiting for so long. Although there are some safety issues related to those medicines especially Bedaquiline, but available study results are promising and the eligible patients in need will benefit from these new medicines. Of course, it is sort of concern to use a medicine, that has not undergone full scale randomized controlled trials through all phases, with thousands of cohorts trying to detect the rarest adverse reaction or event, but let me ask a rhetoric question, has any of the previously used second line anti TB medicines gone through such trials?! The answer is no, but it has not restricted a TB world to use those medicines for MDR treatment – Georgia*

I feel comfortable on using both medicines as the treatment outcomes among MDR-TB patients in our country currently are modest. The new TB medicines offer potential to improve outcomes, reduce overall mortality. The country constituted a committee on New Anti-TB Drugs a year ago. The committee has met 4 times since then and pros and con of introducing these medicines have been extensively deliberated. Drug Controller General of India has already approved Bedaquiline use through national programme based on inputs from programme- India

I feel comfortable on using bedaquiline as the NTP has initiated the plan to use BDQ as a part of regular PMDT program in small scale pilots. The plan will be implemented June 2015. The proposal for funding had been sent to GF and approved. Delamanid not yet been discussed- Indonesia.

I feel comfortable on using both medicines as in the scientific literature and according to the preliminary data published by WHO there are evidence data about efficiency of these medicines in treatment of M/XDR TB patients – Kazakhstan

I feel comfortable on using the new medicines bedaquiline and delamanid for MDR-TB patients treatment, we believe that the new medicines will help shorten the duration of treatment and the quicker achievement of successful treatment outcomes – Lithuania

I feel comfortable on using the new medicines though the evidence of safety is limited however they could be administered for pre XDR cases under strict pharmacovigilance – Pakistan

I feel comfortable on using the new medicines as *Ukraine is high TB burden country. The implementation of new medicines may improve the situation in the country. Nevertheless, it is not possible to say whether it is good to use these medicines in the country till they are registered in Ukraine and the process of use is started – Ukraine*

I feel comfortable on using the new medicines as *they are new TB medicines and preliminary results of TB patients' treatment are very encouraging- Uzbekistan*

I feel comfortable on using the new medicines based on current studies, these two medicines have proved their efficacy in MDRTB treatment, even though there's still lack or evidence regarding safety but I believe that these new medicines give patients new hope to be successful treated- Vietnam

I am still uncertain as the following medicines do not have registration in Bulgaria- Bulgaria

I am still uncertain as we have not used it yet – Myanmar

I am still uncertain as we have never use these medicines in Nigeria before to have the experience and feeling about their use- Nigeria

I am still uncertain about their use as Bedaquiline is a new anti TB medicine after more than 40 years, and we have to protect our patients since there was no Phase III trial on this. Delamanid is also a new

medicines and should be under close supervision and should be regulated in using both medicines to our patients- Philippines.

I am still uncertain about their use as I studied trials data, WHO materials, but we didn't have available for use of patients - Republic of Moldova.

I am still uncertain about their use as long-term consequences are not investigated yet - Armenia.

Would countries recommend the use of the bedaquiline and delamanid?

Most countries recommend the use of **bedaquiline** i.e.19 out of the 25 countries, 5 of the countries does not have an answer to the question. Only 1 country does not recommend its use. With regard to **delamanid** about 16 of the 25 countries recommends its use and 7countries are not sure and 2 of the countries do not recommend delamanid for use.

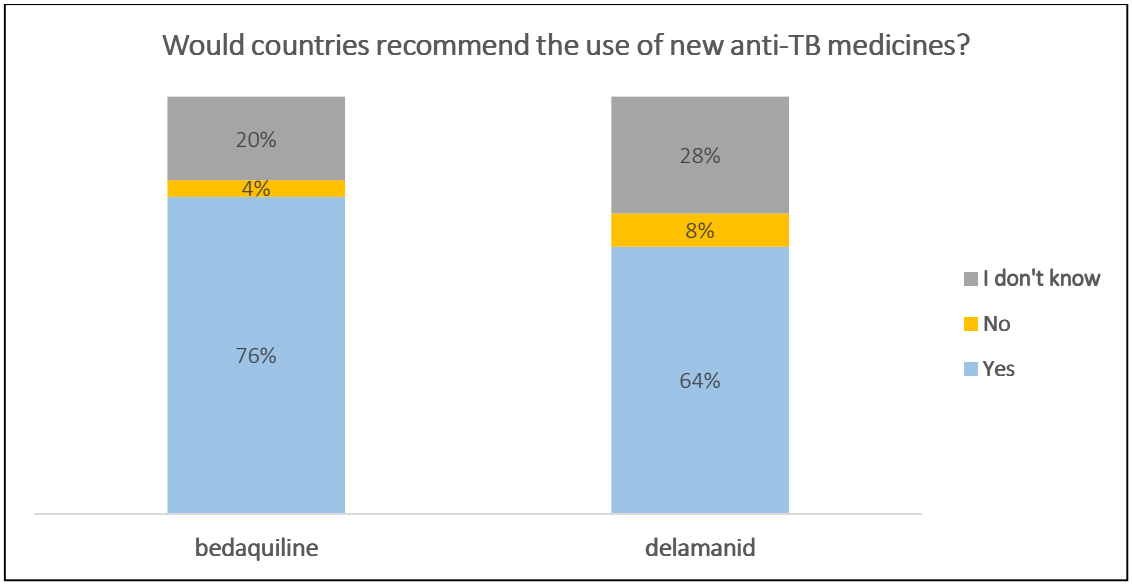

Figure 11: Countries recommend the use of the new medicines.

Do countries have access to companion medicines?

Access to companion Group 5 medicines i.e. Mipenem/Cilastatin/Meropenem, Linezolid, Clarithromycin, Amoxicillin/Clavulanate and Clofazimine is varied in countries. Of the 23 countries who responded to this question, Amoxicillin/ Clavulanate can be accessed in 18 countries, Clofazimine and Linezolid in 16 countries , 14 countries can access Clarithromycin and only 10 countries can access Mipenem/Cilastatin/Meropenem.

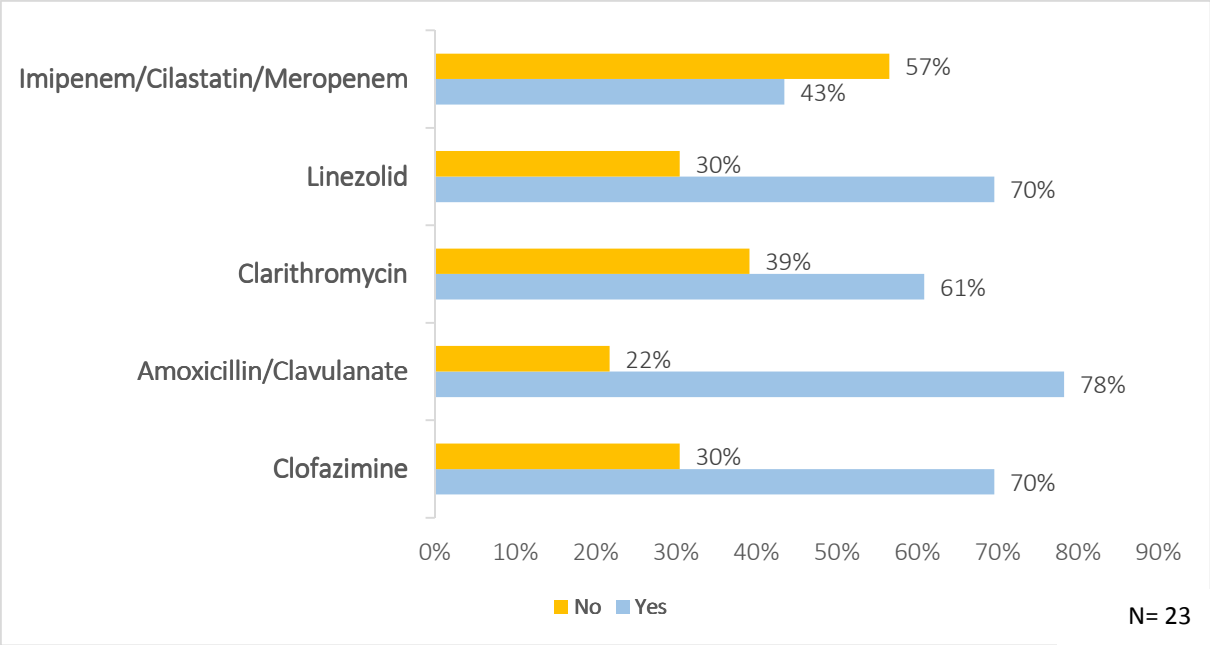

Figure 12: Access to companion group 5 medicines in countries

Discussions:

Results show that most countries (24) have heard of both the new MDR-TB medicines, bedaquiline and delamanid. We know that the FDA approved **bedaquiline** for treatment of adults with pulmonary MDR-TB in December 2012 with WHO issuing an "interim policy guidance" on its use in January 2013, however only seven (**7/25**) of the high MDR-TB burden countries have registered i.e. approved for use bedaquiline between the period of October 2013 – January 2015 with another six **(6)** countries in the process of registering it in 2015. The European Medicine Agency granted conditional approval of **delamanid** in April 2014 along with a WHO interim guidance on its use in October 2014 leading to **three** high MDR-TB burden countries registering its use between December 2014 to May 2015. **Three** other countries are in the process of registering its use for treatment of MDR-TB.

Realizing the prospect of treating drug-resistant TB with the new TB medicines countries have created mechanisms like "compassionate use", "import waiver" allowing pre-approval access to unregistered medcines for patients with no other treatment options. About 17 countries have a framework for use of bedaquiline and this have benefitted 587 drug resistant TB patients, with another 14 countries on the use of delamanid benefitting a total of 50 patients so far. Only 6 of the 7 countries that have registered bedaquiline have a national policy on its use in the country. The 3 countries that have registered delamanid also have a national policy on its use.

National plan for usage of **bedaquiline** in treatment regimens have been made in the 7 countries which have registered bedaquiline and 6 countries who are in the process of registering it, making it a total of **11 countries** on bedaquiline in treatment regimen. Another 10 other countries will make it available through the "compassionate use" framework for access to bedaquiline. With regard to **delamanid**, 3 of the countries registered for delamanid and 3 in the process of registering along with another country i.e. **7 countries** have national plans to roll out delamanid with another 7 countries planning to make it available through "compassionate use "framework in 2015.

Of the countries with plans to roll out both bedaquiline and delamanid only 82 % have budgeted the roll out and mentioned source of funding from donors like USAID, Global Fund (84%) and only 16 % have cited financing from domestic funds.

Barriers to use of **both** bedaquiline and delamanid is that the **medicine is not registered** in the country and not as previously thought to be the cost of the medicines. The cost of the medicine was the second concern for delamanid and third reason for bedaquiline. This could be due to the launch of the bedaquiline donation program by USAID in April 2015. As part of the bedaquiline donation program, countries and organizations can place an order through the Stop TB Partnership's Global Drug Facility. As of April 2015, orders from 2 of the high MDR-TB burden countries were received. The second barrier for use of **bedaquiline** in countries is the concerns about the side effects followed by cost of the medicine, limited knowledge and practitioners not trained in the administration of bedaquiline and few countries who feel no legislation for compassionate use as a barrier. As mentioned for **delamanid** the biggest barrier is the non-registration of the medicine followed its cost, concerns about the side effects, practitioners not trained in the administration of delamanid and limited knowledge of the medicine are equal reasons.

Countries are comfortable using the new MDR-TB medicines, 17 countries are comfortable using bedaquiline and 15 countries on using delamanid and they would recommend the use of the new medicines in treatment regimens.

Conclusions:

Results show that 24 countries are aware of the new medicines but only 28% have registered bedaquiline and 12% delamanid for use. With regards to a framework for "compassionate use" or other mechanism allowing pre-approval access 68% of the countries have access to bedaquiline though this and 56 % for delamanid. Most popular reasons cited by countries for limited or non-usage of the medicines are (i) the medicines are not registered in the country (ii) economic barriers i.e. the cost of the medicine and/or companion medicines among others, (iii) concerns about the side effects, (iv) limited knowledge of the medicines and (v) practitioners not trained in their administration. Question on whether countries would recommend the use of the new medicines, responses show that most countries are comfortable on using the medicines and strongly recommend their use in the treatment of MDR-TB.

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