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Background

The MPP provided an overview of its three-year strategy.[1] It is developing a regulatory information database to support partners who need to access information about regulatory requirements in different LMICs, and has already developed a new access to medicines tracker, table and map, with information on where drugs have been filed, their registration status (including WHO-PQ), and where they are being supplied. The MedsPaL interface will be improved in the coming months.

The MPP is working on upstream access commitments with universities and public bodies, technology transfer - to add strong access language for LMICs at an earlier stage in the innovation process. The MPP has begun working on biologic products.

Medicines on the MPP's priority lists include lenacapavir, and on the watchlist include islatravir, CAB-LA and RPV-LA for HIV treatment, and doravirine. For TB, Otsuka's new drug, quabodepistat – which is in early development as part of a pan-TB regimen; the MPP already has a VL for sutezolid. Bedaquiline is not on the priority list following recent developments with its patent status.

World CAB: Who funds the MPP?

MPP: We are funded by Unitaid, France's Ministère de l'Europe et des Affaires Étrangères, the German Agency for International Cooperation, Japan's Ministry of Foreign Affairs and the Swiss Agency for Development and Cooperation.

Intellectual Property and Voluntary Licenses

World CAB: All of the people in this room dream of a world without patents. You exist because of patents - is this your dream? Are you interested in this dream, and working with us?

[1] https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-launches-an-ambitious-three-year-strategy-for-greater-access-to-medicines-and-health-technologies-for-those-in-need#:~:text=MPP%27s%20strategy%20for%202023%2D2025,MPP%2Dlicensed%20products%20each%20year.

MPP: My dream is everyone getting the medicines they need. That is what really matters for me and that's what MPP works for.

World CAB: Your new strategy – an enabling environment, advocacy, what does that mean? How is promotion of TRIPS flexibilities part of it?

MPP: We mean different things by enabling environment. A license on its own does not mean access. An enabling environment is creating conditions where a VL is the preferred approach. That can mean many different things, including incentives on innovators which can happen in a lot of different ways and through different stakeholders, and by approaching innovators to do more and do better. Flexibilities are sometimes complementary, and it means that innovators are looking at ways to overcome challenges.

World CAB: Last week, in a WTO panel, Charles Gore said, "We don't need a TRIPS waiver anymore to address the COVID pandemic".

MPP: In terms of Charles's statement, I was not there. I think he meant we were not involved in TRIPS waiver discussions, and we are not taking a public stance on the waiver, because it is polarizing, and the people we work with are on both sides of that debate. Since we will not be able to influence the outcome. I do not know what he said, but I guess he did not say it should not happen – nor that it should happen.

World CAB: In the past, MPP VLs were considered better quality, because of their transparency, and their open, non-exclusive, geographic coverage. Your recent licenses seem to renounce these principles. How are you trying to address the degradation in the quality of your VLs such as the CAB-LA VL and the UMIC VL for DTG? The more recent licenses are limited to three suppliers, they impose confidentiality, limit suppliers, and exclude UMICs such as Georgia and Moldova.

MPP: In terms of degradation: I do not think that it is the case. We sometimes say no to VLs for different reasons, including because we do not agree with the territory or with other terms and conditions.

In terms of degradation, I want to push back on that. In the CAB-LA license, many countries that are not a part of the VL, but where the product is not patented, will have access to CAB-LA. Typically, the patent in the country of manufacturer is critical. So even if there is not a patent in the country of sale, they may still not be able to access it because there is a patent in the country of manufacture. That is not the case in the recent license on CAB-LA.

Are we undermining local production? Countries without patents can do local production, DTG and CAB-LA can be produced locally in Latin American countries in which there are no patents on it, but should we stop the Indians from supplying? We are looking at who can scale-up and provide quick access to medicines. Manufacturing of TLD is happening in South Africa, Kenya and Uganda through our licenses. And this is happening through PEPFAR and the Global Fund. As for CAB-LA, we can take a look at the number of manufacturers, is three

the right number? We do not want so many that we crash the market or remove incentives for manufacturers. We should also consider that for some limited markets, it could be a good option not to have too many manufacturers. Currently there is a supply constraint from ViiV on CAB-LA, and we need generics as soon as possible.

Access to Long-Acting Cabotegravir and Dolutegravir

World CAB: Where are we today with the DTG VL for "poor" UMICs?

MPP: We have been adding countries to the DTG VL and in 2020, a new license was signed for the UMICS Azerbaijan, Belarus, Kazakhstan, and Malaysia. When we started discussions with ViiV, what governments told us is that DTG was available for approximately $2000 – the price has gone down approximately 90%. We are hearing from countries procuring now that the price is down from $180-200 per pack to $16 per pack. Is that good enough? Is this enabling access in countries? It is still quite uneven. Belarus has transitioned fast, other countries have taken longer but now seem to be scaling up significantly. There have been some delays along the way – the implementation of a new regional regulatory framework, and in some cases only one company being registered it, which did not lead to competition.

There has been significant progress. It took three and a half years from the VL to the first approvals of generic DTG and TLD. For DTG, this is a good license, it has enabled countries like Chile, which is usually not included in licenses, to procure generics. But not Brazil where ViiV now has a bilateral agreement. In terms of countries outside of the territories where there are patents, the ask is always on the table, it is a voluntary mechanism.

DTG cost $180 - $200 per pack when discussions started. The price has gone down by 91%. Belarus went faster – it has put close to 65% of PLHIV on DTG or TLD. Kazakhstan and Azerbaijan are coming along, but it is not going fast enough. There were issues with regional regulatory frameworks - in some countries we have only one company registered.

World CAB: The actual percentage in Belarus is 44%, not 65%.

MPP: The data we have is on actual supply, not how many people are on the regimen.

World CAB: There are serious limitations to the VL because of clauses, such as the volume-based product access percentage. Malaysia has a separate VL with different clauses and is paying 44 times more for DTG than other countries.

The agreement in Malaysia is the same as in Belarus, Azerbaijan and Kazakhstan and we are discussing with Malaysia to ensure they can procure at similar prices as the others.

World CAB: Colombia has chosen the CL pathway. If ViiV asks you to include them in the VL, so they can avoid a CL, would you accept this? It is sabotaging the CL.

MPP: We tell governments what the situation is, and how we can help them out through voluntary agreements, sometimes we are asked to be involved with company negotiations. Sometimes the governments ask us to be involved - the key is what do the countries want. If the government says they want to discuss with us and explore a voluntary licensing approach we will explore it. Otherwise, we will not. And ultimately, for us to be involved all parties need to be in agreement. We welcome your thoughts as well.

World CAB: Which countries have gone from upper-middle to lower-middle?

MPP: In July the new list comes out. I remember that Indonesia became a UMIC. We do regular checks. it is important because it is much easier to include lower GDP per capita countries.

World CAB: Jordan has become an LMIC but it is not included in the DTG or CAB-LA VL. Can you include them in the VL?

MPP: I did not recall this - we can try to include Jordan. We will look into that, but there is no patent in Jordan. So, I'm not sure it will make any difference in terms of access, as my understanding is that Jordan can already procure generics now. But we will double-check.

Long-acting Cabotegravir

MPP: We have signed three VLs for long-acting technology, some in preclinical trials – such as long-acting, once-monthly injectable TLD from the University of Washington, which is going into phase I, and the Longevity Project for long-acting glecaprevir-pibrentasvir. Also, work is underway on prodrugs of rifapentine and isoniazid, and a malaria long-acting injectable.

You need mature companies to produce CAB-LA. The tech transfer is very important. Community advocacy was very important to get this VL. The VL is like the DTG VL, which is the most impactful and progressive VL. It is only for CAB-LA for PrEP, we could consider asking for a license for treatment as well if there is broader interest. It is critical to get the global health community to make that request. WHO and the Conference on *Antiretroviral Drug Optimization* have not prioritized it – we are happy to discuss it.

The CAB-LA VL covers IP and there is also a tech know-how and transfer from ViiV through bilateral agreements with Aurobindo, Cipla, and Mylan. Cipla will manufacture CAB-LA initially in India and has plans to also manufacture in South Africa, it will probably be available in 2027. Next week we will refine our timeline, when we speak with the generic companies prior to ICASA.

The generic companies were selected through an expression of interest process. We got a number of applications, which were scored through blinded internal and external review. A

short list of candidates was unblinded for onsite assessments and submitted to ViiV for clearance.

World CAB: This undermines the capacity for local production. It is good that your new strategy includes local production, for years the MPP model did not support it. Africa is still the most affected continent, and they are still importing all of their medicines. This is collateral damage from the requirement for WHO PQ. It is good to see you are taking a different model. You could fix the supply issue with regional supply. The countries in Latin America could do that, since there is no patent.

MPP: Should we stop the Indians from supplying because they are much faster? Historically, the global health community has focused on speed, economies of scale, biggest footprint, even so, South Africa, Uganda and Kenya are now making it, what has been driving it is the FDA/WHO PQ approval a lot of companies cannot qualify. I hope transition to WHO listed authorities (WLA) will change this in terms of local production.

For CAB-LA, I am not saying three is the right number, but it's an expensive product to make and the market is highly uncertain. It is not necessarily a bad idea to look at market size and look at producers that can have robust generic competition. We do not need to always have 20 licensees, manufacturers.

World CAB: We ask that you continue expanding general agreements with no limits on suppliers.

MPP: The VL covers 90 least-developed, low-income and sub-Saharan countries. It does not prevent supply in countries where there are no patents. Notably, according to our data, two countries that currently have patents, will have those patents expiring for DTG and CAB-LA in 2026 and 2027 (Colombia and Malaysia respectively).

We sometimes say no to licenses for different reasons, all sorts of them, look at the BMJ paper.[2] The CAB-LA VL brought back critical provisions allowing many countries to have access.

World CAB: Are you currently negotiating to expand the coverage of the CAB-LA license with ViiV? Is there a specific price offer for CAB-LA VL negotiations?

MPP: There is nothing on the table right now. We are always happy to explore including some countries, such as in the EECA region. In terms of expansion into LA-treatment, it is critical to get global health community to make that request, WHO/CADO has not prioritized it, but we are happy to discuss it.

World CAB: The MPP says it does not have enough leverage to ensure that the CAB-LA VL includes all key countries. In Brazil, we made the case for volume. ViiV wanted a bilateral agreement with the government.

[2] https://gh.bmj.com/content/8/9/e012964

World CAB: You mentioned that you have the ViiV product for studies. We are struggling to get a small amount of CAB-LA for implementation studies, for 50 -80 people in Morocco and Mauritius, can you discuss this with ViiV, and discuss commitments to implementation studies in smaller countries?

MPP: This is a really good point. There are going to be delays for access to CAB-LA, because of current supply constraints. We need to get supplies and VLs in earlier – there is a risk that the same could happen with lenacapavir. We need to learn the lesson - to avoid supply constraints.

mRNA Hub

Thirteen of the 15 partner countries have signed the tech transfer agreement, and they have received their technology packages. Assessments of gaps in manufacturing sites are underway.

World CAB: Has the MPP resolved the IP issue on mRNA vaccines in any country?

MPP: We have done a landscape analysis – there are no patent barriers in most LMICs, although a few key patents were identified that require may inventing around - patent barriers may come up. The key challenge is sustainability of effort and investment.

World CAB: How is funding distributed within the mRNA Hub? For example, all of the MPP money - $100 million – went to South Africa. There was no financial contribution to Biomanguinhos/Fiocruz, who got all of their funding from Brazil.

MPP: The first part of the program is to develop the technology. The investment to develop the technology to be shared is happening in South Africa. Therefore, the first bit of funding went to South Africa. When the companies applied to the WHO to be part of the hub, they needed strong support from the government. Over the last year, fundraising to support the manufacturing partners has started. Hopefully there will be funds, but fundraising is harder now than it was during COVID-19. There is going to be a sustainability issue. We will have the platform, but the question will be what antigen, what disease to address. The MPP is helping to fundraise for the program as a whole, but the partners are also fundraising.

World CAB: There are issues about the governance of the mRNA Technology Transfer Program. Can you give us more information about governance, civil society participation, the role of internal working groups, the relationship between stakeholders and regulators? Who makes the final decisions? Would you consider adding civil society representatives to the steering committee?

MPP: The Scientific and Technical Review Committee (STeRCO) supports the WHO secretariat on aspects of critical importance to the successful accomplishment of the objectives of the

mRNA Technology Transfer Programme an includes civil society participation. But decisions are made by the WHO. There is also a mRNA Scientific Advisory Committee (mSAC) that is convened by MPP.

World CAB: Who will own the IP generated by the hub partners?

MPP: The goal of the hub is to share what you develop and to stimulate development of more products. The technology is being developed in South Africa, and then will be transferred to the other partners. The partner takes the technology for free and get the training. If a partner develops IP, they own it, but there is a provision in the agreement that they have to share it, similar to how ViiV licenses its IP. So, the obligation of sharing back is important, and the agreement is public on the MPP website.

World CAB: Can technology be shared outside of the network? Is there a price for it?

MPP: Countries should make a request to the WHO to be a part of the mRNA hub. I do not think that WHO has ever said no.

Community Participation in Boards

World CAB: How does the MPP ensure effective and meaningful participation of communities and civil society in your governance, processes, and decision-making beyond individual representation? How does this work on your board and your Community Advisory Panel (CAP) as compared to Unitaid and GF Boards?

MPP: We have board members but not delegations. I hear your point, that is why we have representatives from different countries and disease areas. We need confidentiality to have a discussion. We have established the CAP to have much more input. We have meaningful community involvement through their involvement in the discussions and recommendations of the Expert Advisory Group. We also have community consultations at global and regional conferences, such as at ICASA.

World CAB: People who go as representatives are confined by confidentiality agreements. They cannot share anything with their communities. This needs to be reexamined. People are there as individuals who cannot report back - so they are useless.

MPP: You need to have confidentiality. I hear you, but I am not sure how it can be addressed. And I do not think they are useless, they bring a key perspective to the process that otherwise would not be there, and that is very valuable.

World CAB: Reconsider your confidentiality agreements. They should not limit community representatives from sharing data.

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Hepatitis

World CAB: What about hepatitis licenses?

MPP: Glecaprevir-pibrentasvir is still under development, it is hard to motivate generic producers. It was not on the WHO PQ list until recently. The broader problem is lack of demand/market, the high cost of its components. We are also supporting the development a long-acting formulation of glecaprevir-pibrentasvir.

In terms of daclatasvir, companies in the VL can supply everywhere except Russia where daclatasvir is patented, and a local company has an exclusive VL for it. BMS will not enforce patents or has withdrawn them in all other countries. But only 38 countries have procured daclatasvir. There may be a sofosbuvir challenge in some countries, but many others are included in the SOF licenses. Those countries can also have SOF/VEL from generic sources, even though it is more expensive.

World CAB: What about bulevirtide?

MPP: It is on our watchlist list, but we have not approached Gilead for a license. We welcome your thoughts and views on that. If there are other drugs, we can also discuss that too.

TB Alliance
Amsterdam – Virtual
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Background

TBA is looking for a pan-TB regimen (for both drug-sensitive [DS] and drug-resistant [DR] TB) to simplify treatment and procurement. TBA aims to treat latent TB infection in one day, and active TB in one month – with LA formulations, which requires a greater understanding of host responses to TB.

DRUGS IN DEVELOPMENT

TBJ-876 is similar to BDQ, but more potent, retaining activity against the most frequent BDQ resistant strains of TB. It has the potential to shorten treatment, be used at a lower dose and improve safety compared to bedaquiline, and its properties are such that it is a good candidate for long-acting formulation. It is currently being evaluated in a phase II trial (NC-009), looking at different doses and treatment durations of a TBAJ-876 – Pretomanid – Linezolid regimen in people with drug-sensitive (DS) TB, compared to the HRZE standard treatment and 6-months of BPaL. While linezolid is known to have side effects, including neuropathies, the NC-009 trial allows linezolid dose modifications (reduction or interruption) as needed to manage side effects, as is recommended for use of the BPaL/M 6-month regimen in DR-TB.[3]

World CAB: Why are you including linezolid in regimens for people with DS-TB? There is already a highly effective standard of care for DS-TB. Why not use sutezolid, a drug that is similar to linezolid, but thought to be less toxic?

TBA: As dose selection for TBAJ-876 is one of the key objectives of the NC-009 study, we need a homogenous population which is why we targeted DS-TB patients for this study. Once we find the right dose, we can move into phase III and target other patient groups. We want to compare TBAJ-876 to Bedaquiline within a regimen to increase benefit for patients, and a well-characterized backbone, instead of combining the diarylquinolines with other new drugs. This will be important to account for any differences between them. The tolerability of sutezolid is not fully characterized and are trying to avoid confounding factors that would make interpreting results difficult. We know how to manage linezolid tolerability; we can dose-adjust and interrupt treatment if needed. In addition, this regimen may shorten

[3] See https://clinicaltrials.gov/study/NCT06058299?cond=Tuberculosis&term=TBAJ-876&rank=3 for more information.

treatment duration which will impact overall tolerability, and patients are dosed with 600mg of linezolid which has fewer side effects.

World CAB: But even the lower linezolid dose can cause neuropathy. People are likely to prefer a few more months of TB treatment to permanent neuropathy.

TBA: You have a valid point. That is why it is so important to understand the tolerability of the HRZE regimen, compared to that of BPaL which this study will provide. Companion drugs of TBAJ-876 are to be determined and the inclusion of linezolid in NC-009 is not to be interpreted as if that decision was already made. The are novel compounds in development that can be considered. As an example, the phase IIa trial of TBAJ-7371 was presented at the Union meeting, we are discussing next steps.

We are conducting an assessment of pretomanid's pharmacokinetics, safety, and tolerability for treating rifampicin-resistant TB in pediatrics. It is being studied only in females at this time, due to a signal of testicular toxicity seen in rodents, but not seen in monkeys. So far 9/36 participants have been enrolled.

BPaMZ/SEM is a post-approval commitment trial in 20 males with DR-TB, treated with pretomanid-containing treatment; changes from baseline in total sperm count and reproductive hormones were assessed. No toxicity was identified among participants. Sperm count increased over time, probably due to TB improvement, and hormone levels did not change. We are engaging with FDA for feedback.

Access

World CAB: Where is pretomanid registered? How many people are accessing new TB regimens and where?

TBA: Over 70 countries have procured pretomanid, for more than 40,000 treatment courses within one year from its inclusion in the 2022 WHO guidelines. In the past, it has taken nine years in the fields of HIV & TB. We have initially focused on 30 countries with the highest burden of DR-TB but have been talking to many more. 150,000 patients translate into 50 kilos per year; one ton per month is feasible. When we have a pan-TB regimen, pretomanid will be used more widely.

World CAB: We know pretomanid is available through the Global Drug Facility (GDF). Could you clarify the extent of global access, and the role of private companies in production and distribution of pretomanid? What pricing negotiations have you engaged in? Which companies do what under their agreements, and how do you and these companies ensure access? What are your plans for ensuring that pretomanid is more affordable? Have you engaged in pricing negotiations? What is TBA's strategy for reaching the lowest possible price for the BPaL regimen?

TBA: Low starting price for pretomanid coupled with strong evidence have supported demand creation. Additionally, pretomanid pricing reduced from $364 to $240 per course, from December 2022 following a volume guarantee that was negotiated with MedAccess. This has helped further. Pretomanid is priced much below BDQ or DLM were at this stage in their lifecycle and a price reduction in nearly 150 countries within days of WHO guidelines was also a first. Note that DLM is still priced at $1700/course ($1200 in select countries.)

After initial introduction, the strategy is to license more manufacturers to create generic competition to reduce prices further organically, increase options, and ensure continuity of supply. Manufacturers are committed through the license agreement to follow WHO PQ/stringent regulatory standards - and not to distribute pretomanid in a manner that is inconsistent with global guidelines/regulations.

A global analysis was conducted, including country-specific estimation for select countries for financial impact of access to BPaL. It could save up to $740 million per year (with potential savings of 40-75% for treating multidrug-resistant TB, and 90% for treating pre-extensively drug-resistant TB) by eliminating systemic inefficiencies associated with longer regimens, including cost of drugs and follow up visits (but it did not include out of pocket costs – just health systems costs) if all qualifying DR-TB patients globally were switched to BPaL/M.

The focus of global health funding is shifting, funding levels are restricted, and there is more competition for limited funding. Considering this, potential for savings for BPaL/M should not be ignored. Civil society can help by rallying people together to slash access timelines and increase demand for BPaLM? Can you please identify areas for collaboration?

World CAB: We have the same goal - but we are moving forward differently. We are unhappy with how TBA is handling pretomanid. It was developed with public funding - you need to give it back to the people who need it. Actual access is not happening, India has the highest burden of MDR-TB, but still does not have pretomanid.

World CAB: We have asked you several times, since 2019, why you will not make your VL public. Many community groups are angry about this – if all these groups are angry, we cannot be wrong. We spoke with Viatris this morning - they say you imposed the secrecy. You are trying to have a monopoly on pretomanid. If this is the way you are handling access, it will never happen. Pretomanid will never be returned to the public. TBA is not a non-profit organization. You are turning out to be a profit-based organization. Who behind the secrecy of your VL?

TBA: Pretomanid was approved in India in 2020, and guidelines written in late 2022. However, the guidelines have not been approved by the Indian MOH so far. Lack of implementation of BPaL/M in India is not due to anything TB Alliance is doing or not doing. We do not understand where exactly the issue is and when it will be resolved as this is an internal matter of the Indian NTP and MOH. We are willing to provide inputs, knowledge and experience we have developed in implementing BPaL/M around the world to India and

have made that known to the NTP. We understand that several other global health stakeholders are also concerned. The communities should also ask questions about lack of implementation to countries.

World CAB: Why are the VLs not transparent?
TBA: The answer is very direct; we work with other entities that have pre-existing licenses which have confidentially clauses. This flows down to other partners. We do not derive any income from any of the access work. We are governed by licensing agreements with other entities. We work in a complex world - in this case, the generic partners that produce these compounds.

World CAB: Can you understand our suspicion, when we see GSK, Gilead, and Pfizer making their VLs public- not just on profit – also production volumes? Do you have royalties on pretomanid in high-income countries (HIC)?

TBA: Yes we do receive royalties on pretomanid sales in high-income countries. I am not able to say what they are, but they are not of real consequence financially.

World CAB: What is your approach to IP: Why are you patenting BPaL in various countries?

TBA: We are not comparable to other PDPs. We develop partnerships and try to lure other manufacturers to the table in an incredibly difficult environment. In this process, a product development partnership (PDP) plays a unique role. TB Alliance is focused on responsible stewardship of TB drugs, and we want partners to do the same.

World CAB: Why is TB alliance, a non-profit organization, actively pursuing an evergreening patent on a combination of lifesaving drugs? Why are you patenting this in EECA and India, and how will you enforce it if it is granted? Maybe it would be easier to follow in the footsteps of J&J which is a commercial entity, and has withdrawn its patent on BDQ.

TBA: I would beg to differ on considering this an evergreening patent. Commercial conditions were set up in different parts of the world. These agreements were set up before we entered the market. The patents were set up to ensure the quality of medicines**.**

World CAB: We have a request from ITPC-EECA/ECAT: Given the announcement from J&J, a commercial, for-profit company, not enforce secondary patents related to BDQ, does TBA plan to withdraw its patent application No 201890614 covering the BPaL regimen, to avoid any confusion around the pretomanid and bedaquiline patent landscape? (Please refer to previous correspondence with ITPCEECA/ECAT, their most recent leher to TB Alliance dated April 12, 2023).

TBA: We would not consider it an evergreening patent, and the use of patients are not blocking access or generic competition. In all countries in the EECA, there is non-exclusivity, apart from Russia. For us, patents are a way to secure adequate control over quality.

World CAB: You are not going to enforce the patents - you are willing to issue non-enforcement letters, which is great news.

World CAB: In 2019, we heard you discuss the link between patenting and quality of medicines– but we do not see the link. Do you have a clear, transparent policy on IP? Is it public? If you do not have a policy on IP, it is time to create one. Just as with the VL, your lack of transparency looks suspicious.

TBA: I do not think our concept in stewarding use of antibiotics properly in the TB field has changed. We as a PDP need to find and manage commercial partnerships –to lure commercial partners to the table in an incredibly difficult marketing environment. We have, in good faith, tried to increase access and transparency. The progress made to date in providing access to BPaL would not have happened organically or as quickly, if TB Alliance did not. Lead where needed, to facilitate the process. I would challenge you to think about the unique role that a PDP is playing to accelerate the timeline to access for new TB regimens.

To follow in J&J's footsteps, look at the difference in models and motivation, they have a profit motive to maintain patents, that is not what a PDP does. In our approach, we started with multiple manufacturers right away. We signed with Macleods and Lupin, and they will compete. We are working to bring costs and prices down. Unfettered manufacturing and distribution without stewardship (including use only as per WHO guidelines and quality as per SRA and WHO PQ standards) will risk losing the drug to resistance and could also push high quality manufacturers out of this already small, fragile and fragmented market; we have a responsibility to be a steward of this drug, else the human cost in terms of loss of life-saving new regimen will be too huge.

World CAB: There are entities that are tasked with quality control, WHO PQ, FDA – it is not your job.

TBA: If there is no license to be enforced, anyone can manufacture and supply the product directly without following SRA/WHO PQ standards. WHO PQ and FDA will have no control.

World CAB: Some of us were at the Union meeting, we were unaware of your consultation there on the shape and color of the pill - which are not important in terms of access. What is your plan on bedaquiline/pretomanid? Will you patent it, is there cost-sharing, what is the agreement?

TBA: We have held these consultations at the Union to try to get as many regions and geographies as possible to consult on the acceptable shapes and sizes for pills. We are developing a fixed-dose combination (FDC) to reduce pill burden – without a commercial

agreement with J&J which previously kept us away from developing an FDC. All the access work we are doing in countries can be transferred to the FDC. There are no royalties. Development has been on-going for many years. Access planning work will start for TBAJ-876 as the compound progresses in development and there will be further consultations. If anyone wishes to provide input to the FDC, please feel free to contact us.

World CAB: You mentioned "other players" that require you to keep the VL confidential - commercial and generic manufacturers. We asked Viatris about this and they now say it is you, not them.

TBA: We have discussed this with Viatris and would like to refute this claim.

Many countries here have national production. When a company develops a generic version, in compliance with regulatory norms, we need a waiver to avoid the impact of patent linkage and a waiver for data exclusivity - which can delay things by up to six years. If you are not going to pursue your pretomanid IP, it would be great for us to have the patent and data exclusivity waivers.

TBA: Understood. There is already generic competition, so we do not see this as an issue. Could you please let us know which countries are experiencing an issue?

World CAB: Royalties from HIC are small. TBA has the FDA voucher.[4] How will you reinvest it? Who are your biggest funders?

TBA: Gates, USAID The United Kingdom's Foreign, Commonwealth and Development Office, and Germany's BMBF (Federal Ministry of Education and Research) are our largest funders - and Australia, although we are currently in a competitive process there. Irish AID and the National Institutes of Health are smaller funders. The royalties we receive are a very small portion of our funding stream of ~$50- $60 million and they are reinvested. To respond to your question, the voucher funding is used as part our strategy to offset deficit spending, it helps us to cover spending for work that is not covered by donor awards; we are looking at how to use it to create a new revenue stream for our work.

World CAB: Will you increase the number of generics manufacturers in your VL beyond Viatris, Macleods, Lupin and Shenyang Hongqi Pharmaceuticals? Africa is dependent on Asian and Indian manufacturers and, in light of lessons learned from the COVID pandemic about the importance of local manufacturing, does TBA plan support local manufacturers in its VL strategy for current and future products?

TBA: The current market for pretomanid is 150,000 people which comes out to about 6,000 kilos of API annually. As a rule of thumb, one needs at least one ton (1000 kilos) per month,

[4] In 2019, TBA received a Priority Review Voucher (PRV) for pretomanid. The PRV program incentivizes research for, and development of medical products targeting neglected tropical diseases, PRVs can be redeemed to expedite FDA review of a drug (from 10 month to 6 months), or sold (sale prices range from $50 million to $350 million.

per manufacturer, to achieve cost efficiencies in manufacturing. Current demand for pretomanid is less than 50 kilos per manufacturer per month on average. It will not be interesting for new manufacturers to invest in pretomanid, and if we force them to, further fragmentation of manufacturing will make it even less viable for current manufacturers, pushing them out of the market and/or increasing costs.

China's current market for DR-TB treatments is about 10K people annually, about 400 kilos of pretomanid API if each and every patient is given the drug. Hongqi is the biggest player in the Chinese market, and we chose a local manufacturer in Pakistan. If a pan-TB regimen includes pretomanid, there will be the need to scale up. However, at the current scale of market even if pretomanid were to be provided to all DR-TB patients, we will destroy the market for it if we license further manufacturers.

World CAB: How do you control drug quality after patent expiry? It is a very dangerous argument, if multinationals decide to block VLs because of worries about the quality of generic drugs. I wish TBA could think of other ways to ensure quality control other than patents. It is not your job - it is a bad solution to a real problem.

TBA: We welcome continued discussion on this issue and would look forward to constructive interaction that involves solutions the World CAB would see as appropriate to ensure poor quality medicines are not used in programmatic settings, which results in the emergence of resistance, or that high-quality manufacturing partners do not leave the field in the future, when other new TB medicines become approved.

ViiV Healthcare
Amsterdam – Virtual
1 December 2023

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Sophie Tamblyn, Communications and Government Affairs Associate

Clinical Updates

World CAB: Do you have any new information on the mechanism of DTG-related weight gain and hypertension?

ViiV: Weight gain is multifactorial and complex to evaluate, specifically in observational databases with uncontrolled biases and considering a 'return to health' effect of ART. There will be a number of studies showing data in 2024, including some information at the Retrovirus Conference. Currently there is no known specific mechanism for INSTIs and weight gain. Increases seen in blood pressure measurements are small, and likely not clinically meaningful, and could be associated with increases in weight. Analysis for DTG and potential association with hypertension is ongoing. More data are coming out over the next few months/years. We do not know of a mechanistic link to blood pressure changes.

World CAB: Any more research of the impact of DTG on mental health?

ViiV: We have been looking at this for many years, we did an extensive analysis for EMA, including depression, anxiety, and whether there is a link with insomnia. We have not found a causal link between sleep quality and mental health issues. DTG crosses the blood brain barrier and is present in cerebrospinal fluid, albeit at low concentrations. The rates of neuropsychiatric issues are low and do not generally lead to treatment discontinuations. We continue to assess this regularly, including in ongoing cohort studies.

World CAB: What about your ARV pipeline? Maturation inhibitors, broadly neutralizing antibodies? And longer-acting CAB?

ViiV: We can give you a separate pipeline presentation with our R&D colleagues – we also have integrase inhibitors in development.

We are looking at ultra-long-acting formulations with CAB as the basis; at three, four, and potentially, six-monthly dosing intervals.

World CAB: Would you consider a trial of longer-acting cabotegravir and lenacapavir?

ViiV: We are in internal discussions on this, regarding a proposal from the AIDS Clinical Trials Group. Lenacapavir plus cabotegravir can benefit some population, such as people with drug resistance who cannot take oral regimens. .

World CAB: Please do a first-line study.

ViiV: As the pipeline progresses, we will continue to evaluate all options for studies in different populations. We have to consider the areas of highest unmet need first, and consider that there are currently many highly effective oral regimens available for treatment-naïve individuals.

World CAB: That did not stop you from developing long-acting PrEP, and it should not stop you from adopting a high-volume, low-profit model for injectable first-line HIV treatment.

Dolutegravir Voluntary License

World CAB: Some countries in the DTG VL are paying much more – their price per bottle is the same as what other countries pay for four years of treatment. This has been going on for a long time. Why is there still such a price difference, and what is ViiV doing about it?

ViiV: Which countries – the general VL or the UMIC VL?

World CAB: It is 2023! In Malaysia, DTG is not even the first-line treatment because of the price – and the situation is the same in the EECA region and many countries that are not included in the VL. This is sad. What are the plans - because we need it.

ViiV: First, at ViiV we feel fundamentally that the world's poorest countries should have the lowest prices, that is why the royalties in the UMIC license have a different structure. In the general adult DTG VL, royalties are due on private-market sales in 10 countries. All other generic manufacturer sales are royalty-free under this license. We believe that countries who can contribute something to the cost of innovation including UMICs should do so. Malaysia had its first procurement in 2023, we expect them to start scaling up now. The regulatory process took a long time. We have added two royalty tiers to the MPP VL (20%-35%-50%-65%) to increase affordability as volume scales up. We feel very strongly that the royalty rates are commercially confidential, and we are not able to share them. However, you can see that pricing has dropped in other countries under the license by 80- 90 % since the VL. This shows that it has been effective; prices drop as coverage increases.

ViiV does not set the prices charged by generics to governments. We are not involved in their negotiations. Logistics, etc. vary a lot and impact the prices.

World CAB: This VL failed to ensure access, either the selected manufacturers have failed and need to be changed, or we need to open the VL to more producers. The obstacle is the

royalties. Why are the royalty rates in the UMIC VL confidential? Royalties should be public information.

ViiV: Data shows that this VL has enabled greater access to DTG than there was previously, and the Governments included in this license have expressed their support and satisfaction with the license. We appreciate that generic introduction uptake has varied across the countries included. There are several factors - there is very high coverage in Belarus for example, DTG was approved quickly. With respect to the number of licensees, the overall market size for these countries is not very big. We need to make sure there are enough manufacturers to drive competition but enable sustainability for the manufacturers. Licensees have not moved at the same speed in all countries. Some countries have only had one manufacturer for some time, and this can lead to a higher price initially. There are lots of factors at play at a government spending level too. We need to also advocate to maintain budget for HIV treatment.

The optics may lead you to believe it is the royalty rate, but it is registration, prioritization, country reduction in spending on HIV, etc., government responsibilities. It reinforces the importance of all parties playing a role. You play a huge role with governments and regulators, and with us.

World CAB: The additional royalty tiers in UMIC are 20% to 35%?

ViiV: We added two additional coverage tiers, so the four royalty tiers that are applicable now are 20%, 35%, 50% and 65% and over. These are on the MPP website. This change happened in October 2023, and it was announced by MPP last week.

World CAB: Our first tender the royalty tier was around 35%. Our importer suffered losses; our government was not able to list DTG on the national drug formulary. I hope you can abolish the royalty system. In UMIC, the current price is very expensive. Hopefully the price will drop.

ViiV: I had not heard that the company had losses. We do not set the price that the generic charges the government; there is not very much we can say on that. We can ask the MPP.

World CAB: You say the price does not depend on ViiV – you have to ask the generic companies. In Belarus we do not have the price; it is determined through a closed agreement between ViiV and the generic company. The market size is not an issue, there are small markets for pediatric ARVs in some regions as well. What we see is that DTG is not reaching our people - it is a failure. We see that with other VLs, the medicines reach the people. The difference is the confidentiality and the royalties - they tell us that they cannot go below the price. Make it transparent, and we will see what the problem is - and we can fix it.

ViiV: We hear the challenge around confidentiality, but I am not able to change this. It is is reasonable for the royalty rates to be confidential for this license. We must reiterate that the generic licensees determine their own pricing, this is not discussed with or agreed with ViiV

as suggested. We have seen coverage go up and prices go down. Governments have said they are very pleased with how the license has operated. This might be an area where we will never agree but will make sure that people in the company hear your views. While the UMIC license may not be perfect and achieve all its goals, we think the VL has been a success and has improved access to DTG-based medicines in these countries.
World CAB: A message for your future VLs - you have had transparency before, such as with the standard DTG VL. Why not just open the market with more suppliers. You are bearing the failure of the MPP. Transparency can fix it.

World CAB: As you remember, you were saying that patents ensure drug quality, but you dropped it, since WHO PQ and regulators check quality, but now you are returning to it. Cipla and Aurobindo were not included in the UMIC VL. Why are you taking on the responsibility for quality?

ViiV: Our position on patents has not changed. They enable fair reward, so we can continue to innovate - we have never said that patents signal quality. Every generic manufacturer has to get stringent regulatory approval under our voluntary licenses, but quality is not the reason for limiting the number of manufacturers - it is marketplace viability.

World CAB: That is their business – they are separate legal entities.

ViiV: If we do not set them up for success, they will not be successful. Pediatric DTG is a perfect example, none of the 14 manufacturers were doing anything. There was not enough space in the market. That is why we entered a partnership with CHAI and Unitaid. We know there is a sweet spot for each product; we actively review that with the MPP. Some manufacturers have dropped out – it depends on market size, thoughtful calculation, taking global health data into consideration, and other inputs to ensure a viable business case or generics will not register or produce it.

World CAB: We think this VL did not deliver. The situation in Malaysia is not acceptable. Access is very slow, and uptake is low. Think about what you are going to do to make this VL work - and do not go into these VLs in the future.

World CAB: Jordan has become a LMIC, when will you amend the VL for pediatric and adult DTG, and CAB-LA, as per your policy?

ViiV: We will act on Jordan and come back to you.

World CAB: Why did you not file a patent for DTG in Argentina?

ViiV: The patents were filed a long time ago. They follow a process between ViiV and GSK, who filed all of the patents - it would have been part of that process. I was not party to that. The process is different now. Our policy towards patenting evolved in 2016 and is in the public domain now. [access-to-medicines-update-2024.pdf (viivhealthcare.com)]

World CAB: ViiV said the reason it did not file a patent was because of the country's treatment guidelines. But in Brazil, you are preventing generic DTG. You said it is according to market size, but we are paying so much more than countries that have a smaller market.

ViiV: DTG patents are robust and were filed many years ago at the early stages of research and development of this molecule. Disease area treatment guidelines are not what determines which country we file for patents in. As a general principle, we operate a flexible pricing approach in middle income markets. We work with governments to achieve a price that matches ability to pay. Brazil purchases a significant volume of DTG, which is why it benefits from some of the lowest prices in the world. However, it is important that UMICs can and should contribute to the cost of innovation. It is also important to recognize that we partner closely with the Brazilian government in a broader context too, including manufacturing and scientific partnerships, so our engagement and the value that we bring goes beyond just the delivery of the medicine.

World CAB: How much did innovation on DTG cost - and how much profit has been made as of now?

ViiV: I do not know how much we spent; I cannot give you a specific number - it includes opportunity cost.

World CAB: How can you price it, if you do not know the price of R&D?

ViiV: We look at the value the medicine offers, the cost of manufacturing, trials; it is quite complex.

World CAB: What is the total royalty revenue for DTG? It is very important – and good to understand this. If royalties are low, it would be good PR for you. Just know that people are struggling to get DTG, which is a good drug. In UMICs we hear a different story from the government and the patients who need DTG. Please do what you can to mitigate this situation, because of the income classification you are pushing Malaysia back to a 2003 situation.

ViiV: We cannot tell you the total royalty revenue for DTG.

Long-Acting Cabotegravir

World CAB: ViiV prioritized DTG, but it is not prioritizing CAB-LA as highly as DTG. We urge you to prioritize it. We are not happy with the territory, leaving out countries like Brazil, which could rapidly scale up – and the limit of three manufacturers.

ViiV: The VL for CAB-LA is only for PrEP and the territory is in line with our public policy on access to medicines which includes all low-income, all least developed countries, all Sub-

Saharan African countries and all lower-middle income countries as determined by the World Bank at the time of signature. Our access work on CAB LA for PrEP has been focused on SSA due to it bearing the highest burden of new HIV infections globally. There is more focus on MICs, so we will see next year how we can sustainably enable access in more MICs. Unfortunately, there is no clear market in many MICs, no long-term forecast to provide confidence for a market. It's important to note that in relation to the voluntary license, these companies are developing CAB-LA at-risk, not knowing if there will be a market for it. Getting more manufacturers, is not realistic or likely sustainable. You could help us with advocating for the need for governments and program implementers to develop and share long-term forecasts volumes. CAB-LA cannot be scaled up quickly. There is a long lead time, and in terms of manufacturing planning, we need to work further in advance than most donors do. We will expand it if it will be sustainable.

World CAB: How will you do this if people struggle to get 50 boxes for sustainability studies?

ViiV: We are building the capacity of our manufacturing and supply chain. A key global donor is stepping in for Africa. ViiV will continue to build its capacity, we have approval in 13 countries with 15 in process. We need to set up for success and first and foremost ensure that there is medicine for participants after the studies end. In sub–Saharan Africa and South America, most of the work is on-going, we have eight large implementation studies, working through approvals and contracting, supply chain and routes. There are smaller projects, demo projects, and people are asking for the drug to simplify that. If it is not a scientific study, we are looking at a different model prioritizing drug provision for implementation studies.

World CAB: Please prioritize civil society and community-based research.

World CAB: When will you do studies in people who inject drugs?

ViiV: This is a different exposure – and a different approach; it makes it very difficult to get a label indication, because it is hard to estimate exposure (sex vs. injection). We are supporting two studies, one in the US for women and one in Uganda for men and women. We acknowledge that there is a clear data gap.

World CAB: This process has been so slow. We just want access to good drugs. Why is the regulatory process slow?

ViiV: The regulatory process/system is very different in each country, that is why it varies so much. The US and the EU have clear processes and timelines and clear guidelines and criteria for accelerated review. Every country has a different approach to regulation. Some countries will only look at a dossier after a stringent drug regulatory authority has approved it. Approval in Australia later helped with registration in African countries as it served as a reference approval. Some countries approve within days of US FDA approval - and some take four to five years to approve a medicine. The African Medicines Regulatory Agency will help

and WHO is working with some Asian countries to streamline the regulatory processes through innovative collaborative procedures.

World CAB: CAB-LA is registered in Russia – but the only indication is for treatment, not PrEP. The leaflet mentions an oral lead-in with CAB, but it is not registered in Russia. What is the indication for oral CAB? Do you need to register it, or is it no longer relevant?

ViiV: The oral CAB lead-in is optional, not mandatory. We have a lot of data to support that it is not needed for durability. The problem comes when you miss an injection, you have to take the tablets in the EU (they are optional in the US). It depends on regulators; you have to consider whether the tablets are needed according to each regulator.
World CAB: This oral lead-in might create a barrier for wider use of CAB-LA, for treatment and PrEP. A doctor who reads the leaflet might get confused, which creates an excuse not to use CAB- LA.

World CAB: If people miss their injection appointment, they might not have the bridging tablets - so how does this help?

ViiV: The optional oral lead-in is causing some confusion. It is a legacy from the development process. People were concerned about hypersensitivity. The lead-in is in the label because the phase III trials were done this way. Most of the phase IIIb trials did not include the lead-in. We are assessing whether these data can be used to update the labels.

World CAB: The VL obliges licensees to prequalify the oral and long-acting-injectable formulations of CAB. Will the VL be amended to include only injectable CAB? This will help with pricing and investment.

ViiV: PEPFAR is not planning to use the oral lead-in. We will get some real-world data without the lead-in. However, the VL does oblige the generics producers to develop oral CAB for bridging and lead-in, based on ViiV's current regulatory licenses it is believed that the generics will need to mirror ViiV's label to secure stringent regulatory approvals. We are in regular conversations with the MPP and the generic manufacturers.

It's important to note that the oral product development component is not that complex - the challenge is the tiny volumes that are likely to be procured in the VL territory. If we are able to remove the oral CAB lead-in, and if we can make the case to regulators for an alternative approach to bridging; it will take time. The process is that we change global data sheets, then country-specific labels.

World CAB: What about the bridging?

ViiV: Alternative oral bridging is known to be fine. We are gathering cohort data on bridging, to get more data to potentially update the EU label.

World CAB: Could CAB be used as daily oral PrEP?

ViiV: Long-acting is the future; we have no development program for CAB as daily oral PrEP.

World CAB: What is the timeline for giving CAB-LA PrEP to countries that did trials, and the plan for post-trial access?

ViiV: We have a rollover study that people can enter – it is three years long. If there is no local supply available, we will look at other post-trial access options, but we will need a clinic and provider to give injections. If people stop using it after the trial, it will be hard to get them back into a study. Whilst ViiV is providing CAB LA product for use in a number of large implementation studies, ViiV is not sponsoring these studies, the sponsor has the responsibility for post-trial access. We are open to discussing how it can be done but it is not our responsibility.

World CAB: What is ViiV planning/thinking about the impact of lenacapavir on the market for CAB-LA? How will it impact volume, price, etc.? The PURPOSE trials could end early. Is there a shelf life for two- month injections of CAB-LA?

ViiV: We welcome choice and options. We do believe that CAB-LA has strong superiority data. We should not wait for a new thing to come, we will take the risks (such as with donors – will they wait for lenacapavir, which creates inertia for CAB- LA). Fewer doses of lenacapavir does not mean its price will be lower. Too much hesitation might compromise options in the future.

World CAB: Community groups are not getting the product they are asking for to conduct implementation studies. Where are you conducting implementation studies? Brazil, South Africa (6 or 8 studies) - we need those studies and community groups.

ViiV: We are building the capacity of our manufacturing and supply chain. It is also important to note that this capacity is also used to support treatment. Africa would be next region to get product for PrEP. We have invested a lot this year to increase capacity. We have regulatory approvals in 13 countries, and 15 more have been filed. There is a significant number of ongoing implementation studies. We will get data in pregnant and breastfeeding women.

World CAB: What volumes of CAB-LA will be procured by PEPFAR and the Global Fund? For which countries? What is the timeframe? What is the registration status for CAB-LA?

ViiV: For the eight implementation studies, the product is not being procured through PEPFAR. We are close to finalizing agreements with MSF and a couple of governments. Initial procurement is going through PEPFAR, led by central PEFPAR versus country level funding/ working with COP (Country Operational Plan) cycle. You need to ask PEPFAR about volumes and countries. The Global Fund is a little behind, they will get initial supplies in 2024, more in 2025 and 2026.

World CAB: Did you remove confidentiality and other problematic provisions in your supply agreement with MSF?

ViiV: Yes, we have removed the confidentiality requirement. Our 2024 CAB-LA non-profit price for the public market in low-income, least-developed and sub-Saharan countries is £23.50 per vial, sold in 25-vial pack.

World CAB: What about private markets in LMICs?

ViiV: Our focus is on public markets. We have not heard a call for private markets in low-income, least developed and sub-Saharan countries. Pricing in MICs will be tiered. We are figuring out what our pricing looks like, considering the epidemic, volume, etc. and workshopping this with PEPFAR and the Global Fund to progress on it.

World CAB: What is the access strategy for countries that are excluded from the CAB-LA VL? Differentiated price? An upper-middle-income country VL?

ViiV: There is no clear market for any of the excluded countries, and three sublicensee are developing the product - at risk. To expect more manufacturers to do this is not a realistic view of the economics of the marketplace. CAB-LA has a complex manufacturing process and a long lead time for it to be supplied. We will expand their number if we know the needs.

World CAB: You have high income countries for profit and low-income countries for PR - you are worsening the situation for MICs.

World CAB: If I am a lower-middle income country and I want injectable PrEP in 2025, can I order it from ViiV, or do I need to wait until 2027 or 2028 when generic versions are available?

ViiV: That's a very broad question with a lot of variables so impossible to give a definitive answer. We are working to build capacity but we do this based on our understanding of demand and so we need clearer viewpoints on what countries want and when, especially in MICs.

World CAB: But you can supply high-income countries, but not middle-income countries?

ViiV: We have clearer inputs on what they are planning. We are happy to have conversations with individual governments around access. This product has only launched in the US at this point, the second group of countries to introduce it will be in Sub Saharan Africa where the number of infections is the highest. We need the commitment from governments and not just from the community to ensure that we can enable sustainable access.

World CAB: This means that any new medical technology is quickly accessible for rich countries, just like the mRNA COVID-19 vaccines. We have to wait until the rich are served. We cannot access new technology until 2028.

ViiV: We are more than happy to discuss this with individual countries. We have shifted the dial and are open to conversations with MICs - we need conversations and commitments.

World CAB: It is difficult to create demand for products that do not exist. You are creating a middle-income country access gap.

ViiV: We agree there is a gap, this is not exclusive to HIV medication. We are open and willing to address this and are working with different partners on this and how to approach it. We are thinking about having a dialogue, all parties need to share in coming up with a solution. Individual companies cannot solve this on their own.

World CAB: For Chemonics and PEPFAR, how many countries are there?

ViiV: About 69 countries. Ultimately, they tell us which countries they are buying for. For some we need country-specific packs, for regulators. We cannot share information about the volumes. PEPFAR can say, it is their information.

World CAB: Which are the first PEPFAR countries? Is this information in the public domain?

ViiV: I cannot answer on behalf of PEPFAR – but I can check if we can share this with you, less than five have already been procured for, and GF has not procured yet.

World CAB: The pricing confidentiality is shooting communities in the leg who are doing demand creation for your – they are in a position to say "look, this is a new drug, you should buy it" - but governments have to wait for the tender proposal to discover the price. If you keep the price confidential, we cannot convince them to allocate the budget.

ViiV: The middle-income country prices will remain confidential. The company is willing to engage with governments.

World CAB: Colombia chose a CL pathway - are you discussing an access strategy, are you discussing with MPP?

ViiV: As you know we don't believe CL is the best way to generate access. We are disappointed in the decision of the Colombian government. We are engaged in conversations to better support Venezuelan migrant population. We are open to further discussions around the challenges in Colombia and what the role is that we can play.

World CAB: Are you discussing it with MPP?

ViiV: Not as of yet. No, we have not had discussions with MPP around UMIC licenses yet and this is not something that the business is considering at this time. You have also clearly stated that you do not believe the UMIC license has been a success, so is that something that the community would actually welcome in this case?

World CAB: Will you confirm that the MPP VL allows supply to Colombia?

ViiV: If a CL is issued by the Colombian Government, in those circumstances the MPPF VL does not prohibit supply to Colombia by a generic manufacturer. Otherwise, Colombia is not included within the scope of the adult DTG Voluntary License.

World CAB: Will you enforce data exclusivity in Colombia, or waive it - to allow your VL to work?
ViiV: We have to check with our legal and regulatory teams, we are not sure if it is relevant for Colombia.

World CAB: It is fully relevant for other provisions of the VL, if you come with a solution and block another strategy it will never work.
ViiV: We will come back to you.

Fostemsavir

World CAB: Is there any real-life data on Fostemsavir, besides what is available from clinical trials?

ViiV: We are getting more real-world data on fostemsavir from the US-based Opera cohort- this will happen slowly.

World CAB: Please explain the high price of fostemsavir in Brazil, where ViiV is charging roughly US$2,700 per month? Providing fostemsavir to the 500 people in Brazil who need this drug will cost 6% of the country's entire budget for HIV medicines. We could provide first-line treatment for 40,000 people for that amount of money. We are here, together, on World AIDS day. You have said your vision is to not leave anyone behind. I think that is false. We are paying for innovation, but the benefits are not shared.

ViiV: There is a commitment to enable access where there is medical need. Fostemsavir is important for a small number of people because of its place in the treatment pathway. It costs a lot to produce – we had to build a separate, dedicated facility to make it. This means the price is high in countries, but we work with national authorities to enable sustainable access – those conversations have been had. There is a compassionate use program, there are routes to enable access to people who need it to construct an active regimen.

World CAB: Do you have you an estimate of the production cost for fostemsavir?

ViiV: Yes, but we are not able to share it as it is commercially sensitive information. We can share with you information about the compassionate use program – which is used before drugs are registered. There are different pathways for cost and affordability. For compassionate use please access: ViiV Healthcare - Compassionate Use (idea-point.com)

Multiple Languages

World CAB: What do you do if package leaflets need to be in two languages - does this impact drug pricing?
ViiV: We do have multi-language leaflets for some products. We will have them for CAB LA in the future, I do not think it has a huge impact on cost – it might impact cost efficiency of production facilities, but this would be a small impact; it can take a year to get regulatory approval of package insert changes.

World CAB: Which languages are available?
ViiV: English, Spanish – and in Portuguese for Brazil. it is difficult to answer, in sub-Saharan Africa we will have an English pack and an English/Afrikaans pack for South Africa

World CAB: In Moldova we cannot use medicines from Poland, sometimes repackaging is necessary, how would you proceed in such cases?
ViiV: We would have to go back and check. We sell packs that are legally approved for the country it is sold in.

Participants' List

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10	Sergey	Golovin	EECA	Russia
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12	Anahit	Harutyunyan	Positive People Armenian Network	Armenia
13	Anastasia	Homeniuk	100%	Ukraine
14	Giten	Khwairakpam	Treat Asia	India
15	Jockey	Kittitrakul	TNP+	Thailand
16	Veronika	Kochubei	100%	Ukraine
17	Sergey	Kondratyuk	ITPC	Ukraine
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33	Aditya	Wardana	IAC	Indonesia
34	Henminlun		DNP+	India