

MENACAB

2017 REPORT

WIN - MPP - PHARCO - PHARMAS - BECKER

Report prepared by Pauline Londeix

AKNOWLEDGEMENTS

ITPC-MENA is grateful to the following individuals for their guidance and support with the preparation of the 2017 MENACAB Meeting and report: Morgane Ahmar, Alia Amimi, Elie Ballan, Souhaila Bensaid, Alim El Gaddari, Aziz Ur Rahman, Othoman Mellouk and Pauline Londeix. The meeting has been supported financially by ITPC Global, Robert Carr Network Fund and Positive Action.

ABOUT ITPCMENA

The International Treatment Preparedness Coalition in the Middle East and North Africa (ITPC-MENA) is a network of people living with HIV and their allies who work together to improve access to treatment and prevention services for HIV and its co-infections including viral hepatitis and Tuberculosis. We are based in Marrakech, Morocco, and our activities cover the MENA region.

Address: 158, Boulevard Abdelkrim El Khattabi, Gueliz, Marrakech 40000, Morocco

Tel: +212 524 423 355

Email: info@itpcmena.org

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LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ALCS	Association de lutte contre le sida (Morocco)
ABC	Abacavir
API	Active Pharmaceutical Ingredients
ARV	Antiretroviral
ATP+	Association Tunisienne de prévention positive
AZT	Zidovudine
BIC	Bictegravir
BMS	Bristol Myers Squibb
CAB	Cabotegravir
CAB	Community Advisory Board
CEO	Chief Executive Officer
CL	Compulsory Licence
DCV	Daclatasvir
DTG	Dolutegravir
EMA	European Medicines Agency
EMRO	Eastern Mediterranean Regional Office of World Health Organization
FDA	Food and drug Administration
FDC	Fixed-dose Combination
GNI	Gross National Income
GSK	GlaxoSmithKline
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HLA	Human Leukocyte Antigen
IPO	Quality management IPO model??
ISO	International Organization for Standardization
ITPC	International Treatment Preparedness Coalition
ITPC-MENA	ITPC in the Middle East and North Africa

LIC	Low Income Countries
LDV	Ledipasvir
LGBTQ	Lesbian, Gay, Bi, Trans and Queer
MENA	Middle East and North Africa
MENACAB	Middle East and North Africa Community Advisory Board
MIC	Middle Income Countries
MOH	Ministry of Health
MPP	Medicines Patent Pool
MSF	Médecins sans frontières
MSM	Men who have Sex with Men
NGO	Non Governmental Organization
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
PREP	Pre-Exposure Prophylaxis
R&D	Research and Development
RPV	Rilpivirine
SOF	Sofosbuvir
TAF	Tenofovir Alafenamide
TB	Tuberculosis
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UMIC	Upper Middle Income Countries
UNDP	United Nations Development Program
UN	United Nations
US	United States
VL	Voluntary Licence
WB	World Bank
WIPO	World Intellectual Property Organization
WHO	World Health Organization
WHO PQ	Pre Qualification Program of WHO

PREFACE

About the MENACAB:

Since the beginning of the HIV epidemic, Community Advisory Boards (CABs) constituted an effective tool to link communities as real partners with researchers and drug manufacturers; to educate people living with HIV and their advocates, to disseminate information about research and drug development and to discuss access strategies. In 2004, ITPC organized World CAB meetings in partnership with i-Base UK and Gay Men Health Crisis (GMHC).

Since then, several regional and national CABs have been set up, in partnership or independently from ITPC. This is justified by the need to address national and regional specificities and also to meet with local/regional representatives of drug companies as well as local research teams. Treatment and access strategies may also differ from one region to another.

The MENACAB has been established in 2014 in a joint initiative of ALCS and ITPC-MENA. The first meeting took place in 2014. Today, the CAB is hosted by ITPC-MENA and run by a new steering committee appointed in 2017.

The objectives of the MENACAB are to:

- Improve access to strategic information for people living with HIV and/or HCV to equip them for effective advocacy for Universal Access at country and the MENA regional level.
- Develop and strengthen a network of treatment advocates.
- Provide expert training on current treatment issues and opportunities to meet with doctors, researchers and pharmaceutical companies.

This report covers the second MENACAB meeting held in Marrakesh Morocco from 23rd to 24th November 2017. Eighteen participants from eight countries of the MENA region attended the meetings.

Selection Process of Participants:

The CAB steering committee developed a selection process through a public call for candidature and online application. Selection criteria included :

- Individuals living and working in a country of the Middle East and North Africa region
- Persons living with HIV, HCV, HBV, TB or key population
- Knowledge on intellectual property
- Knowledge on drug pipeline for HIV, HCV, HBV and/or TB
- Experience of participation to a CAB meeting
- No conflict of interest with the pharmaceutical industry

During the selection process, special consideration was given to people with hepatitis C or HIV/HCV and representatives of key populations. The committee also considered regional balance and gender parity.

Meeting with ViiV Healthcare



ViiV has a comprehensive portfolio: NRTIs, NNRTIs, protease inhibitors, integrase inhibitors (12 ARVs) and a strong pipeline (two-drug regimens DTG-based, maturation inhibitor with possible combinations with DTG and/or cabotegravir (CAB), long lasting two drug regimens (cabotegravir + RPV), attachment inhibitor for highly experienced patients, next generation agents with game-changing potential, prevention (cabotegravir), etc. ViiV supports more than 300 programs addressing the needs of people living with HIV, including education, care and treatment projects. In MENA, ViiV supports increasing awareness of Positive Action for MSM and Transgender people. ViiV's access strategy is based on research and development, product donations and expanded access programs, capacity building, patent licensing, pricing, manufacturing and distribution. The company has a tiered pricing policy in Middle-Income Countries factoring in GNI and the impact of the epidemic in each country on case-by-case basis. A key pillar to access approach for DTG is to file for approval in all parts of the world. To date, Tivicay® has been filed in more than 100 countries. ViiV granted royalty-free voluntary licenses to 17 generic manufacturers to date. (From presentation by ViiV)

Question: Abacavir (ABC) is considered as preferred 1st line regimen for pediatric use by WHO. However, it is not very used in our region by physicians because of fear of hypersensitivity reaction. Do you have any data on the risks of reaction to hypersensitivity for children? Especially in our region? Is the genotype/hypersensitivity test compulsory or recommended before the treatment initiation? And if so, is there any effort of ViiV Healthcare to make it available in resource-limited countries, especially as it is recommended now by WHO new guidelines?

ViiV Healthcare: In terms of the data there are studies that vary about hypersensitivity. We did a meta-analysis. The result of the analysis is that the risk of hypersensitivity is less than 1%. As a company we must abide by the label that recommends having the HLA testing done prior to use of abacavir as this is in the best interest of the patient. I can find the major analysis and share that with you. Otherwise, there is still a lot of use of ABC in sub-Saharan Africa. The test is recommended, but not widely done. Studies show that the genotype that leads to hypersensitivity is very low in Africa. How is it in the MENA region? It is unknown. But I imagine there isn't enough data in this region. I would suggest you contact Martina Penazzato who leads the WHO-led Pediatric ARV Working Group (PAWG), who gives advice on using ABC in resources limited settings.

Question: Do you think it is for everybody?

ViiV Healthcare: We wouldn't say it was. The safety of patients is most important. If you speak to the WHO they might give a more programmatic response from countries.

Question: What are you doing to make the test more affordable? Do you have the technology to do the test?

ViiV Healthcare: No, it is a third party.

Question: Maraviroc has not been a very successful ARV. How do you explain this? Do you think it is still a drug that is useful? If so, in which cases?

ViiV Healthcare: Maraviroc requires a tropism test before you can take it. It's an expensive test, a few hundred US dollars, and the FDA was slow to approve it. There was mixed reviews on dosing. Most first line patients are on once daily regimens. Maraviroc required twice-daily dosage, which limits its use. Beyond this, it is a successful product and I think it still does have a role for some PLHIV.

Question: We are interested to hear more about Cabotegravir. How does it work? How often does it need to be injected? When do you think it will be available?

ViiV Healthcare: For Cabotegravir, in therapeutic use, we are in phase 3 trials. The studies are looking at every 4 weeks (monthly) injection. But we are also looking at 8 weeks. In prevention we are looking at Cabotegravir on its own every 8 weeks. The studies should be completed by early 2019 for treatment. So we are looking around 2020 for initial regulatory approvals. For prevention, the studies are not time bound (they are event-driven), so it would be dependent on the infections in the different studies. That's when the timing of the PrEP side will be determined.

Question: What is your patenting policy in MENA region? Will you file patents everywhere or only in a few countries? What will be your criteria? Your CEO recently announced that GSK would not enforce patents in low-income and lower middle-income countries... Does this mean, not filing patents in the future? Or filling patents and then not enforcing them?

ViiV Healthcare: Our policy is to give generics production rights in LMICs, LDCs, SSA and LICs via voluntary licences. And we don't issue voluntary licences until we have drugs that are marketable.

Question: Does this apply to all GSK drugs or just HIV drugs, the not filing patents policy?

ViiV Healthcare: Yes, this approach to patenting applies to all GSK medicines in LICs and LMICs as per Andrew Witty's statement in April 2016. I am not an expert on GSK, but this commitment was made by Andrew Witty when he was CEO. GSK is actively trying to work on how to operate those commitments for the other disease areas GSK is active in. The mechanisms don't exist the way they do in the communicable diseases space. But I can connect you to someone if you need more information.

Question: We are very interested in dolutegravir, can you tell us in which countries of the MENA region have you registered the drug? As for the countries where you have not registered your product, what are the reasons for this? Can you give us a calendar when this will be done?

ViiV Healthcare: Some countries just approve what the US has already approved. But some countries have no regulatory process, which is not something that we as a company can change. This has an effect across the board as no company can register their medicine. Some countries can access medicine through other processes or via waivers. So this is where activism is important to let countries/policy-makers know that patients cannot access medicines because the processes aren't set up.

Question: In the case of Algeria they have DTG in the guidelines and it has been confirmed by your colleague, so can you speed up the registration?

ViiV Healthcare: I have been following up on this on a monthly basis and haven't found anything. We need a formal notification from the Algerian Ministry of Health before we can submit DTG to the regulator. I don't know where my colleague heard that DTG was in the guidelines but we will double check.

Question: The MPP license seems to include a provision that allows supply of generic medicines to countries outside of the license territory if there is no infringement of patents. In such cases, will ViiV Healthcare allow registration of generic versions or enforce data exclusivity when applicable to prevent the registration of the generic version?

ViiV Healthcare: The license agreement allows manufacturers to provide drugs to countries where there are no patents and which are not in the licensing territory and we will not stop that. As for data exclusivity, we are not sure there are many countries where this is an issue, and we haven't had any complaint about that. We do provide waivers to MOHs that are following proper procedures. We have done this in Ukraine, for example. We haven't seen a country that doesn't have a patent but has data exclusivity, but we would look at the request if we got it.

Question: I am from Tunisia, and like many people living with HIV, we are desperately waiting for DTG based regimens. We can't anymore support efavirenz side effects, and some of us have resistance to efavirenz. Our Minister of Health received a letter from the MPP saying that even if Tunisia is excluded from the MPP voluntary license, we can still be able to procure DTG because there is no patent granted on DTG in Tunisia. However, we were surprised after the announcement in September of the Gates foundation/CHAI deal on DTG to see that Tunisia is not included to the deal. We are lost... Our government is lost... Can you confirm if your interpretation of the voluntary license is the same as the MPP? Do you allow MPP licenses to supply Tunisia with generics? The same question applies to Libya and Lebanon?

ViiV Healthcare: That is correct. There is no patent in Tunisia for DTG. The challenge is that there is a law that suggested data exclusivity may apply in Tunisia, but we are trying to get clarity if that is being enforced and if that could be a barrier. As of July 2016, Tunisia is now a LMIC according to World Bank Classifications, so what would be helpful is to send a formal request to ask to be added to the voluntary licence territory since it is now eligible as an LMIC.

Question: Do you need a request, you can't do it on your own?

ViiV Healthcare: A request is preferable; we need to know that someone wants to access in this country by this route.

Question: Can the request come from civil society?

ViiV Healthcare: I think it would be sufficient. But a ministry request would be stronger.

Question: For Tunisia, it will not be a problem, but Libya can be problematic because of the situation that you know in this country.

ViiV Healthcare: Libya is actually an UMIC, so is not eligible for inclusion in our voluntary licensing territory. We have been trying for 3 years with Libya to provide HIV medicines. We are ready, but we don't get a follow-up from the purchasing organization. We are trying, we are open, we are ready to discuss with them. But it is very difficult to have any interaction with them.

Comment: I think you should put the person in charge of this in contact with ITPC-MENA Director of programs Alim El Gaddari. I remember when you were trying to send shipments to Libya through Aids for Aids we were successful. If you are interested in doing something for Libya we can work on it together.

Question: Your voluntary license on DTG has been issued in 2014, where DTG was expected to be a third line drug. Since then, information has changed and DTG is likely to become part of preferred first line regimen. With this information, we expect you to come with a new access plan including more countries since we are speaking about a drug that is not needed only by few people on treatment failure... But your response has been disappointing with the amendment to MPP license adding only 4 countries. Are you willing to review your voluntary license soon?

ViiV Healthcare: We fundamentally disagree that DTG would only be a 3rd line treatment. It was designed to be used as a 1st line, though we did also look at its use in people with high levels of treatment resistance as well. We always studied it as a 1st line. We continue to have discussions with CHAI and others to help countries with access. We added 10 countries to the license last year. I don't see any intent to further expand the territory. The license already covers over 90% of adults and 99% of children in developing countries. To be transparent, we are not going to review the license for DTG.

Question: For 3 years, with support of ITPC-MENA, we have requested from you several times to include Algeria which remains the last and only country in Africa to not be able to have access to Dolutegravir in generic version. Without success, so far, we have no other choice than to request our government to issue a compulsory license (CL) and to be frank we are working on this. What would be your reaction if Algeria issues a compulsory license?

ViiV Healthcare: The reason why Algeria is not a part of the license is because it's defined as an UMIC. We use the WB criteria to have equity in our classification for inclusion in our voluntary licenses. Other companies pick countries with no rationale. We use it because it is public and we do not control the classification. There is no rationale to include Algeria without including other UMIC countries that we have no intention to include. There are some countries like Brazil and Russia where we have commercial interests that are important for ViiV to be a globally sustainable business, but if we include UMICs that has a significant impact for us. We are ready to enter Algeria. We need them to put DTG in their guidelines so we can then register and then we can negotiate a price with them.

Question: Frankly, I don't think that Algeria or any MENA country constitutes a strategic market for HIV drugs. GSK and Pfizer are making huge profits on other drugs. Wouldn't it be better for you to make efforts on HIV to preserve your market on other drugs than to engage in risky behaviors for your image with prescribers and governments if you continue banning people from accessing your HIV drugs?

ViiV Healthcare: This is an area where we are not going to agree. This is a question of what the government priorities are. This isn't a question of affordability. We can work with you to break down some of those barriers. ViiV Healthcare is a separate entity to GSK so we do not look at their portfolio to look at returns. It's not how our business finance operates. Algeria is not a massive commercial market, but it is a reference market. Because it's an UMIC we cannot have a rule that we don't apply to all other upper middle-income countries. It's a question of equity, which is why it's outside of the licensing territory.

Question: If the market isn't important for you, you are not going to make any efforts. So you lock them out so it won't be a reference?

ViiV Healthcare: In comparison to Brazil it is not as important as a commercial market. But it's not to say it's not important. I don't want to suggest that we aren't committed. What is blocking us is not on our side. But we cannot commit to reclassifying Algeria to include it in the VL territory when it is an UMIC. We have looked at other measures like the UN but we cannot cherry pick rules because we don't think it's fair for individual countries within the same WB country classification.

Question: On what criteria have you decided on the included and excluded countries for these licenses? Only on the WB classification then? Are you aware of what is happening in Lebanon? Do you know we are 4 million Lebanese people and we have 1.5 million Syrian refugees? 500,000 Palestinian refugees and 250,000 Iraqi refugees? Do you think a country like Lebanon can face such a situation? Why don't you take conflicts, humanitarian crisis as additional criteria for your access program? We have heard that after the Ukrainian crisis, and currency devaluation, ViiV Healthcare has taken decisions to support Ukraine to not enforce patents and allow generic supply. Why not Lebanon? Or Jordan? Both facing much worse situation?

ViiV Healthcare: There has been discussions going on with the team locally and our international team about Lebanon and refugees and migrants. We are committed to understanding the humanitarian situation. I cannot tell you the solution, but I can tell you we have been discussing this for the last 4 to 6 weeks. I will go back and follow up and let you know where the thinking is heading and who the stakeholders are. I don't know who is part of this discussion and I am not a part of those discussions.

Question: The crisis in Syria is 6 years old now... Why did it take so long to start the discussions?

ViiV Healthcare: I can't tell you why we waited so long to begin these discussions.

Question: Most of the countries of MENA are now classified by the Global Fund to fight AIDS, tuberculosis and malaria as high disease burden...

ViiV Healthcare: Once again, we use the WB classification, and then all of sub-Saharan Africa, which means we don't only use income, but prevalence. The prevalence in the region is low, even if certain key populations have a higher prevalence. We can look at this, but including LIC and LMIC and sub-Saharan Africa is a good strategy.

Comment: Even the GFATM is not talking about prevalence, but is talking about "disease burden". They consider North Africa as high burden. Maybe you should change your thinking from prevalence and follow the GFATM.

Question: 3 years ago we raised with you the fact that Jordan was excluded from the Dolutegravir pediatric voluntary license. You acknowledged that it was strange situation. What have you done so far to solve this? Many countries that have higher income than Jordan are included in the license! Do you have issues with the Government of Jordan? If it is the case, are you punishing children living with HIV (very few) for this?

ViiV Healthcare: Jordan is in the pediatric license. It is also now a LMIC, so it will go in the license for adults as well. The DTG registration is different from the license agreement. What I showed is where ViiV Healthcare is registering products so that generics producers can use our dossier as a reference to register. I can't tell you when it was submitted. The approval process can be lengthy; we can't predict when approval will happen. With a formal request we can include it in the adult voluntary license since it is now classified by the World Bank as a LMIC. There is no grievance between the Government of Jordan and us and we would never make a political statement around health, HIV, it is a world issue and we don't make political statements. We wouldn't exclude a country from the licensing territory or registration because of political circumstance.

Question: 3 years ago the person from ViiV told us the same thing and 3 years later nothing has happened?

ViiV Healthcare: I don't know what happened there. This wasn't an issue raised when I arrived in this role. You have a commitment from me. It is an LMIC so it will be added to the license.

Question: For countries excluded from your voluntary license like Algeria, what is your price policy? What are the criteria to define prices? We have heard that you offered Morocco initially a price of £70-80 per month (\$1.600-\$1.700 per year). And knowing that ViiV considers us (Algeria) as richer than Morocco... Are you serious to think that the government of Algeria is going to agree on such a price for DTG alone while we are buying 1st line regimen today for less than \$100 for 3 drugs?

ViiV Healthcare: This is a commercial pricing approach and I haven't been part of discussions concerning Algeria, because of this hold-up with the guidelines. I don't think they got to the point of a pricing position. I can tell you we will look at the GNI of the country and will include sitting down with the Ministry of Health and whoever the purchaser is. And try to get to a place that is workable for both sides. Does the country want to use it for 1st line and for how many patients? What is the volume demand over a 1 or 2 year period? There are a number of parameters where there is flexibility but that will have to be done with the Ministry of Health.

Question: Governments won't decide on volumes if they don't know the price. They won't put it on first line if they think it will be more expensive than what they are paying now. They want to know, how much will it cost in generics. Is it possible that you would offer Algeria the same price as generics? What is your cheapest price today? Botswana?

ViiV Healthcare: We can't make the drug for that cost [generic price]. This is the difference between generic business models and ours. The generic price of Aurobindo for DTG 50mg communicated at \$44 per patient per year in SSA, we cannot manufacture at that price. The price in Botswana is the cost of production plus distribution around £20 (\$28,3) per pack, so per month. That price is only available for LIC and sub-Saharan Africa. Since we got approval in 2013 in the US we have more countries using the product and bigger volumes and are working on

2nd generation production to get prices down and pass on those savings. This takes time, and then we have to go to every regulator to change the labels, but over time this will allow us to sell the drug at a lower price. But in Algeria we cannot sell at not for profit price.

Question: I have been living with HIV for 17 years. Like most people in my case, I started with early drugs that were more toxic, with heavy side effects just like your AZT. My husband died because he could not have access to Dolutegravir. Don't you think, we deserve today to have access to better drugs like Dolutegravir just like a compensation for all what we have suffered so far from side effects of your drugs from which you made lots of profits even when they were toxic?

ViiV Healthcare: Thank you for sharing your story and sorry for your loss, it sounds like a difficult situation. There is no easy answer to your question. I have a fiancé and children and I care about people. I do hope that drugs like DTG being broadly available will help more countries establish 3rd line treatment programs. I don't think it's an issue isolated to your country. There are many countries that don't have 3rd line treatments. I hope that DTG will last long as 1st line but that countries will also have good 3rd line. Is it a human right to have access to better drugs? I think regarding old drugs, there are people who wouldn't be here today if it weren't for those earlier drugs, I understand that people had side-effects, we support people moving off these older drugs. There are still a huge number of people on DDI. We support getting people off these old drugs, because there are better options. That is my view. We would love for everyone to have access to DTG, which is why we have these conversations. But we do have to balance that with the investments in the future. We can only invest in these new modalities if we get a fair return because if we don't, our investors will stop putting money in. And as a company that is only focused on HIV that would be the end of us which would be bad for PLHIV. We have to balance access and sustainability. I know it doesn't give you the answer you're looking for. We have to work together with people like you and governments who value treating people with HIV fairly.

Question: You have been explaining the reason for the tier pricing and voluntary license based on the WB classification. I think this is a problem. Do you know what the average incomes are in countries such as Algeria? Lebanon? Jordan?

ViiV Healthcare: No, I don't.

Question: Sorry, I know this is a MENACAB and not an Algeria CAB, but I want to come back to the Algeria case. My people in Algeria both from civil society and government know I am meeting with you today, and I need to tell them TODAY what do you plan to do. We have been discussing with our governments during the past weeks, they want to give us DTG, but it is very unlikely that they will pay more than what they are paying today for a 1st line. Will you give us same price as generics meaning \$40? You can also allow us to access generics by including us in the license or committing to not enforce your patent in Algeria? I want a sort response: YES or NO? How will you go to ICASA in a couple of weeks and say that your are providing access to ALL Africa except ONE country: Algeria? Do you realize the violence of such a behavior? It just looks like your are declaring a war on a country!

ViiV Healthcare: We already replied to that question.

Question: I think ViiV should be more innovative when considering their classification like conflict crisis, use UN criteria on burden instead of prevalence, marginalized groups and key populations. So you should care about this. Please tell your colleague from the research side if she can send more information. People are tired of taking pills. If you have something that is CS friendly please send it. You will receive applications from the MENA region and we will send you a summary of this meeting with contact information to follow up, and you can discuss with the individuals.

Meeting with the Medicines Patent Pool



The Medicines Patent Pool (MPP) is a voluntary license mechanism that has negotiated more than 10 voluntary licenses on HIV and viral hepatitis B and C medicines with originator companies since its launch in 2010. The MPP's mission consists into improving the access to treatments against HIV, HCV and tuberculosis and to promote innovation thanks to voluntary licenses and a community of patents. The MPP works with a large number of partners, industry, civil society, international organizations, patient groups and governments. MPP licenses have some specificities: insuring the quality of products, being flexible (non exclusive licenses, no restrictions). MPP also promotes information about the patents status, through Medspal. 13 MPP licensees are developing DTG 50mg. 4 are already filed with the US FDA, 3 through the WHO pre-qualification system. By the end of 2018, MPP is expecting 5 more filing. 5 are developing scored IR tablets and are expected to file also by the end of 2018. 2 MPP licensees are planning on development of 50/10mg, which is likely to be filed in early 2019. Registration of DTG/TDF/3TC, is a priority product for most MPP licensees. 5 further filings are expected by mid-2018.

On HCV, MPP has a license on daclatasvir to license 10 generic manufacturers to supply 112 countries (including about 75 MIC), and on ravidasvir currently in clinical trials in Malaysia and Thailand). The geographical scope will complement DNDi's licence for a total of 130 countries. (From presentation by MPP)

Question: Regarding your presentation. Is there sometimes situations where you have some products but no one is interested in getting a license from the MPP? Do you have sub-licensees for all your licences?

MPP: In general, we have an interest with a generic producer to produce the drug. I will double check with you. They are interested and we know more or less the filing date and date of approval. We have an impact study on our website and you can see which ones are already developed (please see the slide: "les producteurs generiques avec les licences du MPP"). In some cases the drugs are already on the market, in others they are in development, I can't say the exact number. I gave the example of DTG. If you have a more specific question I can find the answer.

Question: During a negotiation with a pharmaceutical company, based on which criteria do you decide on the geographical scope of the license?

MPP: We always have the mandate to ask to include all upper and lower middle income countries. The limitation is that it is voluntary. We try to make the case, but sometimes they decide in an arbitrary way, because different companies have different policies. Some will accept to include some middle-income countries, but there is no real explanation. Other companies refuse to give any licence like Johnson&Johnson. We try to present the information we have and collaborate with governments to the specific countries for instance Algeria. We manage in some cases but it is always difficult. We have CS requesting to the companies. It's important to work with governments and CS to try to convince the companies and make the case.

Question: Lebanon has the highest rate of refugees, MPP has a global responsibility, you cannot say that it depends on the company, how will you support us?

MPP: We don't present the MPP as the only solution for access. The MPP is part of the solution. We manage to include some countries, which is good because it's better than nothing. We include a lot of countries and PLHIV. It's awful that we cannot manage to include all of them, but it's the limitation of this mechanism. And the MPP recognizes that. So we suggest you work on other strategies in parallel. We can try to get Lebanon included in the VL, we can make efforts, but if it doesn't work, CS and governments have other options. You can issue CLs. But this is not in the MPP hands, because our mandate is only to try and convince the companies. But if we can't, it's only part of the solution.

Question: Are governments involved in the negotiation process? If yes, how? If not, why?

MPP: In particular, with the Egyptian government we have a lot of bilateral meetings at the highest level. Our Executive Director (former E.D. Gregg Perry) met with officials from Egypt. They were mostly interested in the HCV. Sometimes the result is positive, sometimes not.

Question: When you negotiated bictegravir (BIC), how did you work with governments who are in and out? Or for example in the case in DTG?

MPP: There is no specific time to get from the government. It's a new drug and they don't recognize the immediate need. So there are not openings to engage them. But that doesn't prevent us from working with the governments in the future. We try to get these agreements signed as quickly as possible so that the sub-licensees can start producing the product. So if we don't manage to include all the countries, we still sign the agreement. We try to have more than the status quo. But we can collaborate after the signing of the license for those that are not included in order to amend the license. The most important thing for us is to have the best possible terms and conditions, even if we don't have all the countries. Then we can modify and include other countries, the red lines that we have the respect are the terms and conditions of the licenses.

Question: Over time we have felt an improvement of your licenses with more MENA countries included. And suddenly with BIC we realize that you come back to your early licenses. What happened? How long did you negotiate with Gilead? What did Gilead offer initially? What did you get more?

MPP: The negotiations are completely different from company to the other. You can get something from ViiV Healthcare that you can't get from Gilead. We didn't decide not to include the MENA countries, but it depends on the company. Gilead never accepted these countries. It's difficult to speak across drugs and companies. We don't have a VL for sofosbuvir, and there is no rule on how companies will negotiate, and they have different interests with different drugs.

Question: Did you have a BIC patent landscape while negotiating? There's nothing on BIC on Medspal?

MPP: I will report this fact to the MPP. You still have the patent information for DTG in the license agreement. If you go to the end you have the patent status included. Then you can find where they have patents. We are working on this, and the expansion of Medspal, so I hope we can include this information. We had this information when we were negotiating and if you read the annex of the agreement you have this information.

Question: What do you do after a licence is signed? Do you consider your job is done? If excluded countries want to issue a compulsory license, will you publicly support these countries?

MPP: We communicate with all the countries that are included in the licenses, and their HIV programs, if they exist. Sometimes if we have requests from countries to be included that are not, we work together with them. Our mandate is only VLs, so it is difficult to support CLs. We are trying to convince companies to enter into a voluntary agreement, so we cannot ruin the trust by pushing CLs. But I can tell you that we have countries that ask for technical information, for example Peru on atazanavir, and we provided information to them on which generic companies were ready to provide the drug. But we do not issue public statements. We are ready to work with Algeria and discuss the best way to collaborate. I have experience doing this in Latin and Central America, but I am interested in working with this region. If you have specific needs I can discuss with you.

Question: During the negotiations, do you have any redlines you can't go beyond that determine what is acceptable for you or not? Can you share this? Have you ever refused a licence? Why? With whom?

MPP: We have some redlines. It's hard to have hard redlines which we have discussed with CS around the world. The negotiations with the companies are very different. If I have a specific redline I will have limitations in negotiating. So we don't have redlines in writing. We do have specific things we always include. The compliance with TRIPS flexibilities and CLs. We always have these clauses in our licenses. The content of the license goes through an Expert Advisory Group from people outside the MPP who give us their opinion on the content of the license and this report goes to the Board of the MPP that decides if the license is good or not. I don't think we have refused, but we are still in negotiation with some companies that refuse to accept a minimum standard. The status quo is measured in terms of access, not in terms in another license. There are patents but there is no access. If they are not accessing DTG because there is a patent, then it's better to sign an agreement because then there will be access.

Question: During last MENACAB meeting, both ViiV Healthcare and the MPP promised to review the pediatric licenses to include children in Jordan (very few by the way). Jordan is still excluded, how do you explain this? Did ViiV Healthcare refuse?

MPP: I am not sure about this particular case. I can ask my colleagues. What normally happens is that we go back to the company to include the country in the license. If the company doesn't accept it, there is nothing we can do. I imagine that this is the case, but I will check with my colleagues and send you more information.

Question: I am really shocked to see that a country such as Palestine, which relies 100% on the international aid, is excluded from your licenses. Do you or your partner companies consider that the government has the ability to pay?

MPP: Like in the case of Iraq, it's because we don't have access to the patent information. I participate in the WIPO meetings and they invite delegates from the patent offices and I try to get information from the WIPO secretariat to reach the patent offices. So if we don't have it in the database it's because we don't access to this information. Why, I don't know. If CS can help us contact the right person...

Question: When you make a present to someone you make sure it arrives to the person. Don't you think? I am from Mauritania, we are in most licenses however your drugs are not in our countries. It was already the case with the DTG pediatric licence 3 years ago, but the medicines have not arrived to us yet? My husband died of HIV 3 years ago because he did not have access to 3rd line treatment. Mauritania is one of 47 countries where no one is interested in registering. How do you ensure that your sub-licensees file for registration at country level? And that drugs are accessible to those in need? Mauritania is one of 47 countries where no one is interested in registering.

MPP: In the clauses of the licenses we have provisions that say we will follow up with the generic companies. We have a small liaison office in India. After the licence, we work with them to know where they are in their development. We ask them to report on their registration, for countries that are included in the license. But the generic producers are also private actors. They decide where they want to produce. Sometimes the problem is that they try to register in a country, but they don't succeed. You can help us determine where are the problems, and then we can follow up with the company to find a solution. The size of the market is also important. We reach 98% of the people living with HIV with the countries we cover. I know that is not the response, but if the problem is

with registration or the MoH, or a problem with the company we can try to resolve them once we identify the problem. We negotiate the license, but the problem is not solved there. We work with generic producers, but we cannot predict the problems that will arise in each country due to the licence, we are a small organization. We try to remove the obstacle of the patent, and if we know of a problem we can help resolve it. In Mauritania you are in the licence, but you have to identify where the problem is, then we can speak with a generic producer or find an organization that will provide the drug. Just because you are in the licence doesn't mean you automatically will get the drugs. Identify the problem and we can work together.

Question: BMS refused to provide clinical data to sub-licensees in India so they can register.

MPP: We solve the problem of patents, not the problem of registration. This isn't MPP. We don't know what the problem is, is this the MoH not approving the registration on time? We will go to the Mauritanian government and find out which drugs are missing and then come back to you and see what we can do.

Question: In Tunisia, we received a letter from the MPP informing us that even if we have been excluded from the DTG, we can still procure generics because no patent has been granted. However, we were surprised not to see Tunisia listed in the last CHAI and Gates Foundation announcement on TLD. Can you clarify if we can or not procure generics?

MPP: We asked CHAI, Unitaaid and the Global Fund, we explained that we sent letter to the countries that don't have a patent but can buy generics. If they don't have Tunisia on the list, that doesn't mean you can't buy generics. But it means that you don't have the right to have it at the negotiated Gates Foundation price. But Tunisia will have to negotiate a price with the Gates Foundation. The companies believe that they can sell the drugs for more in certain countries.

Question: Have you sent letters to excluded countries too to inform them that you tried to negotiate on behalf of them but you were unsuccessful?

MPP: In principle we send letters to those who are in the license, not those who aren't. But we do send letters to governments and CS in countries that we think could enter the license, on a case-by-case basis. It's not just because of us that new countries enter the licence; it's also CS that pushes for CLs that put pressure on the companies.

Question: It's important for the MPP to inform countries that don't get included.

MPP: It is possible to get Algeria added, if they push for a CL, then it's possible. It didn't work with Peru, but with other countries it did. It is easier for us to advocate if we have the support of the government.

Question: How did you set royalties in DTG licence? Do royalties apply even when patent is not granted? For instance, in Egypt patent is filed but not granted.

MPP: We set the royalties during the negotiation. And we set them for all the countries. For certain licenses we included other countries that the company didn't want to include by raising the royalties. The Latin American countries negotiate together for their drug prices. It's better to pay the royalties and be in the license than to negotiate with the company alone.

Question: You have been successful to revise DTG licence and add 4 countries? Why these 4 countries? What led to this situation?

MPP: My role is to work with governments and CS and not with the companies. So I don't know why specific countries were included after. But it was due to a strong demand from All Ukrainian Network that put pressure on the company. It's important to work directly with the government. If there is a specific case you are interested in, contact me and I will respond by email.

Question: Who are you negotiating with now? Which product?

MPP: See slide with this information. It lists the drugs and companies. These are the priorities. All negotiation we start are listed on our website, through press statements.

Question: Do you think that you are adequately consulting with civil society and PLHIV? Especially in MENA a region where you have problems to include countries?

MPP: I don't know if we consult enough. We have been meeting with ITPC for some time. We can always do better. We work with every developing country, so it's difficult to work closely with any particular country and understand everything at stake. But you can identify problems and we can find solutions together.

Question: Do you have any quantitative objectives of licenses to be signed per year/period?

MPP: We need to comply with UTD which is our funder. We need to comply with a minimum number of licenses, which is agreed upon with UTD.

Question: I prefer you don't sign a license for a few years if it means not signing a bad one.

MPP: If we wait until we sign the ideal agreement. We signed DTG before the approval, which was important, because we managed to get the product on the market in less time. Some other times, it took many years to get the product to the market. In the case of TAF and DTG we are getting generics to the market quicker. We are doing the same analysis for the essential medicines list. Are we only going to approve these drugs or are we going to look upstream to see what is coming. That doesn't mean that the content of the licence is affected. We still have our minimum standard and try to get the maximum we can get. The terms and conditions are the maximum we can get. If the company is ready to include these small islands we don't refuse them. But it's difficult to include UMIC. The companies think that they have the money to pay, Brazil, China, Mexico are never included.

Question: When we look at your license there are many included countries where there is no patent. Most of the countries that are excluded are where there are patents. You struggle in the countries where there are patents.

MPP: In the case of Jordan MPP negotiated the pediatric licence not knowing how many kids had HIV. It was 20. The case of Lebanon is it's not a rich country. They have almost as many refugees as citizens. There is a need to be more work on the country context. For the problem in Tunisia and Morocco, we need to pressure CHAI because there is a misunderstanding. It's also your responsibility to assist countries and be creative to not ruin your relationships with Pharma companies. It's important to inform them, and explain the options. You should do it publicly, but if not at least do it in private. We will send you the different points we have discussed and any issues, as well as the list of participants with their contact information.

Meeting with Pharma5



Pharma5 is a Moroccan pharmaceutical company and a producer of many generic medicines. The firm also exports in particular to sub-Saharan African countries. Pharma5 put on the market in Morocco in 2015, a generic version for sofosbuvir. Some time after, a generic version of daclatasvir was also put on market. In September 2017, Pharma5 marketed the first Moroccan produced HBV treatment. In 2010, Pharma5 became Saudi FDA approved, and 2013, GCC approved. Pharma5 sells in 40 countries, more than 100 specialties and developed partnerships with care institutions and various Ministries of health. (Ranked 12th in IMS for francophone Africa). Pharma5 exports SOF in 12 countries: Benin, Burkina Faso, Benin, Ivory Coast, Gabon, Guinea, Mali, Togo, Congo, DR Congo, Mauritania and Niger. (From presentation by Pharma5)

Question: You just presented your products currently on the market. Do you have any others HCV or HBV drugs in the pipeline?

Pharma5: sofosbuvir and daclatasvir as fixed-dose combination.

Question: Can you talk a little more about the SMAD study? What is the efficacy rate?

Pharma5: It is an independent study made by SMAD that has not been published yet. We will share the results with you.

Question: Apart from your certifications mentioned in your presentation, how do you guarantee the quality of these specific products? Can you develop further if you have any plans to prequalify your products by WHO or any stringent FDA?

Pharma5: We are at the beginning of the process of pre-qualification with WHO. It has taken time to complete the pre-process. To ensure the quality of our products, we are always in process of pre-qualification and follow the scientific data. One important element is the importance of quality raw materials. We audit our providers, and their production sites. Most of our raw materials come from suppliers prequalified by the US and the EU, and are required to meet their standards.

Question: Have you conducted any bio-equivalence study? For which products? And where? If you haven't why?

Pharma5: It is mandatory to do the bio-equivalence. We can test in vitro or in vivo. Morocco follows the recommendations of the WHO. There are countries that go beyond the requirements of the WHO. For Hepatitis C, we did our test in vivo. We wanted to be armed if our product is called into doubt. In regards to Hepatitis C the bio-equivalence in humans is not required. In vivo is more expensive and complicated. The minimum cost for in-vivo bio-equivalence testing is around \$200,000.

Question: What happened to the application of marketing approval of SOF+DCV in Morocco, that was just rejected? What your plans now?

Pharma5: We will keep fighting, we won't give up. This is a good way to lower the price. These two molecules are well known and already in generic version and clinical trials have been done. When we talk about new molecules we do clinical trials. We are respecting the WHO guidelines, but the MoH of Morocco doesn't see it this way.

Question: Are the countries in your slide those where you have registered in? Do you have any plans to expand further? For example to Lebanon?

Pharma5: All the countries on the map are countries where we are registered and have sold products. Today we are going to construct a factory in Ivory Coast. But Lebanon is a strategic country. We have registered in Lebanon. But we are not selling products yet. It took 2 years to register ourselves in order to provide products, and now we have to register each product.

Question: How do you explain the price difference between your products and Egyptian Generics that are less than \$100 per cure?

Pharma5: There are several reasons that explain the difference. We launched our company when the raw material was expensive. And we set out prices at the lowest price at the time. The prices have since fallen. When we launched our product for HCV, the country announced plan for eradication of HCV. In Morocco, we had a problem that is delaying our production. The invitation to tenders was not answered [it was launched, but then cancelled again at the end of 2017]. People who aren't covered by private insurance or who are covered by the RAMEL [health insurance for the poor] have to get the medicine at the hospital and use Peg Interferon because the MoH still has a large stock. We provide our product at the price that existed 2 years ago, and the prices have fallen enormously since. We inform doctors of new medications to treat HCV. We are not selling what we were supposed to be selling in these two years time. Pharco has access to an exclusive national program, and treated a million of patients. They say they produce their own raw materials. We are far from their volumes. But our products are quality. We provide our product at the lowest price that existed at the time.

Question: If Pharco enters Morocco, will you lower your price?

Pharma5: If Pharco follows all the regulations that are required in Morocco, and offers the product at their price, it's clear that we cannot follow them. Before we offered our product in Morocco and in Africa patients didn't have

access to this treatment. If someone is going to dump their product in Morocco... We would have to stop producing HCV medication. This would discourage future efforts in Morocco and even beyond. It was counted on us to produce just ARVs, daclatasvir, sofosbuvir and tenofovir... When we started, things were not clear, except to make a quality product. We didn't know how many people we would treat. We created a plan to eradicate HCV, but you need to test the population, which is not likely. What was realistic was to say that we can provide 15,000 treatments. We still have enough raw material for 6,000 treatments.

Question: Can you tell us what are your prices in the 12 countries where you are exporting now? What is the price for Mauritania?

Pharma5: 220 euros (\$273) per box for SOF. The same price as in Morocco. There might be slight differences in price due to distribution within the country, but there won't be a difference in our price.

Question: Why don't you export daclatasvir? Is it a registration issue?

Pharma5: Sofosbuvir is not used alone, but with daclatasvir, or ledipasvir. So we would export both products because they are used together, as two pills.

Question: Given the massive price decrease of API's in the global market, are you considering decreasing your price? How? By when?

Pharma5: As I said, we are still paying the API the same price as two years ago...

Question: What is your profit margin on HCV drugs as compared to other medicines?

Pharma5: I wouldn't talk about figures, because it's minus minus minus. On HCV, we are not making a profit. We have just launched, and you don't profit right away after you launched. We made some investments. Compared to our other products it's loser even two years later. But we are proud to make this product available in Morocco and beyond. And proud that Morocco is associated with access to treatment. The benefit to our citizens is important to us. But we do not make profit on this product. Globally we have a profit margin of 7-8%. But we have losers products.

Question: Where do you procure your API from?

Pharma5: The non-certified producers sold the API for half the price, but we weren't willing to take the cheaper option. Today we pay the price that I mentioned earlier. The raw materials we still buy are based on the price we negotiated two years ago. We are currently renegotiating the price, but it's difficult because we don't know when we will need the product. We buy from China and India, like everyone else. For sofosbuvir and daclatasvir, which are still sold together, but we have diversified our sources.

Question: How can you be competitive in the countries where you export given the prices of the concurrence (Pharco and the Indians producers - under the voluntary licenses)? Aren't you worried to lose the current market?

Pharma5: As far as I know from the invitation to tender, we are the only company. I am worried, because the quality in Morocco is higher. We are at a US, European level. The perception that the Africans have is that Moroccan products are of a superior quality. We send Moroccan doctors to do training in sub-Saharan Africa. We have been ready to launch this combination product for the last 6 months. What matters for us is our quality, and the recognition of our brand in Africa. It's a question of quality, Once you have a large quantity, you divide.

Question: How do you justify the price for TDF (\$30 per month) in comparison to lowest generics available (\$2-3 per month)? And also, do you have any interest to produce HIV products? Which ones? Are you interested in HIV, treatments and PrEP?

Pharma5: Yes, but some information are confidential, we have to go through different things first, there is a pre-qualification issue and other issues that we have to look at.

Question: What is your contribution to the Moroccan national strategic plan? We heard in the beginning of the process that you wanted to fund an epidemiological survey and contribute to fund testing strategy for HCV?

Pharma5: We are ready to get involved in the strategic plan. But it is shocking that we were not consulted at all. We were never invited to any meeting. Why? I don't know. There were doctors who consulted with us, on the price.

Question: How do you promote scientific information about new therapies among physicians and the public?

Pharma5: We are frustrated in our limitation to act. We are not authorized to approach medical professionals. Our training continues, we go to conferences to discuss HCV. Unfortunately our action stops there. We don't have the right to communicate with key populations or even with generalists. If we get official permission from the authorities we can act. When it comes to the larger public it is a question of resources. We cannot substitute our authority. We are still a small company, and to have a larger presence is expensive. We are trying to grow.

Question: Can you speak about your Noufissa Foundation? Is there any activities related to Hepatitis? Does it operate only in Morocco? How do you plan to work or engage with civil society?

Pharma5: We are always ready to assist when there is a request from the MoH. We work in Morocco and internationally. We are active in environmental protection and culture. We are available to CS in terms of access to treatment and to help in the country and in Africa. Our problem with HIV is that we need to be pre-qualified by WHO.

Question: During the IAS 2017, you promised our colleagues in Venezuela to help with donations of medicines, can you update us if this happened?

Pharma5: Mr. Aguais reached out to us about providing treatment in Venezuela. We need to have an authorization from our MoH and get approval from the Ministry of foreign affairs. We made the request in July. But let me get more information. My father created this company to make sure Moroccans had access to treatment. Get back to me with the situation in your countries; let us know what the barriers are. And if it will be possible for us to bring low priced drugs to Algeria for example, we will do.

Meeting with Pharco



Pharco is a key player in generic production of hepatitis C treatments (SOF and DCV). The company is producing independently from Gilead's nor BMS's voluntary licenses. Pharco is currently developing a medicines to be used together with sofosbuvir: ravidasvir. The company exports to 57 countries around the world. On HCV, Pharco launched the first API factory in Egypt, specialized in manufacturing DAAs, under the GMP requirements. Pharco produces each day more than 10,000 patients months of therapy. The number of sofosbuvir produced is 1 million packs. Pharco completed a comparative clinical study on 300 genotype-4 patients (sofosbuvir+ravidasvir) and had a success rate exceeding 93%. As for 2018, the price for a cure is \$270 and by 2030 Pharco aims to decrease it to \$80. Pharco is planning on developing the export of our products to low and middle-income countries at two different prices, one of LIC and another one for MIC. (From presentation by Pharco)

Question: Apart from providing drugs, how do you contribute to the Egyptian National Hepatitis Plan? Do you support any raising awareness, testing support campaigns or other activities?

Pharco: This is done in cooperation with the Egyptian MoH. We cannot do testing alone. We have to cooperate with the health authorities. We need hepatologists.... We make the test with our money, but we don't make the diagnostics alone, as we are not allowed. We fund all the rapid tests, and the HCV PCR test is funded by the government. With regards to raising awareness campaign, the infections were coming initially from the injections. Now the infections are coming from barbers. We have launched a campaign, which is not our job, but the government's. Our main effort now is on the diagnostics.

Question: Can you update us with the status of WHO pre-qualification? For which drugs did you apply for? How did the process go? Any lessons learned?

Pharco: Only sofosbuvir. We are in round 17. We are suffering from the pre-qualification. The WHO is very tough. They were surprised to see an Egyptian/Saudi company. It's been 2 years that we submitted. They inspected the API plant in Saudi Arabia, which was approved two weeks ago. They approved the plant in Alexandria five days ago. Now we are waiting for the approval for FDA and EMA? WHO is tougher than the other two. The procedure is too long. We have learned from our mistakes, so we are going to apply for daclatasvir first quarter of 2018 for WHO PQ. They approved Mylan, and Hetero already. It's seems a little political.

Question: Until you get the WHO pre-qualification, how did you guarantee the quality of your drugs so far?

Pharco: We have been providing sofosbuvir for 2 years now and then daclatasvir. We have registered sofosbuvir in 12 countries. We were checked by MSF, the GFATM etc. and said that our product is good for treatment. The process is continual, to qualify your facility. The UK government asked to verify our quality in order to provide drugs for a clinical trial in Vietnam.

Question: Have you conducted any bio-equivalence studies? For which products? and where? If you haven't why? And if so, is it in-vitro or in-vivo?

Pharco: Our sofosbuvir trial was in-vivo. And the WHO confirmed bio-equivalence of our trial in Jordan. And now we are doing daclatasvir. They did a comparison of 6 companies and we are number 1 for sofosbuvir. For daclatasvir, we are also number 1. The in-vivo trial costs \$120,000.

Question: How do you manage to practice such cheap prices? What are your current volumes in Egypt and abroad?

Pharco: The price of the API went down from \$100,000 dollars to \$10,000. We are bringing the price of API down. When you are treating 1 million patients, you need 3 million boxes. The API cost \$3,500 per kilo. We bring the intermediates to our facilities and they manufacture at a high quality. The API is going down, \$3,000-3,500 is the cheapest you can get. Through the MoH the price is \$26 per box of sofosbuvir and daclatasvir is \$9. At the pharmacy it is \$60 for sofosbuvir and \$10 for daclatasvir. MSF price \$12 for daclatasvir.

Question: What is your market share today in Egypt? What was this market share last year? What happened to other suppliers?

Pharco: 13.2% is our entire portfolio. We have antibiotics. For HCV, we are 60%. 40% is supplied by other 15 other Egyptian companies. There is no change since last year. We are trying to increase market share with our diagnostic products, so we can find the patients and treat them with our products. No one is working with the government the way we do.

Question: What prices are practiced by your competitors in Egypt?

Pharco: All companies are charging the same price.

Question: What are your margin profits in Egypt?

Pharco: 3-5% profit margin.

Question: Do you benefit from any kind of support from the government or any other parties? Taxes exemption?

Pharco: I don't know exactly. I don't think we do. Our vision is to cure people. We are not looking for wealth. We are devoted to HCV elimination and then we want to make a switch to manufacturing HIV API.

Question: Can you talk about your export policy? Do you have any plans to export to countries represented here?

Pharco: We would like to enter into Morocco. But we are restricted. We have a partner here, Spimaco, a Saudi company. They have a manufacturing facility. We are submitting for marketing approval of sofosbuvir. The registration is planned in the second quarter of 2018.

Question: Do you have any plans to open manufacturing sites outside Egypt? If yes where?

Pharco: How much capacity does Pharma5 have? We are in Saudi Arabia. We are registered in many countries. Algeria is very difficult to register. They prefer to manufacture locally.

Question: What do you think about the prices applied in Morocco (\$900, 15,000 persons treated) and Algeria (1200\$, for 6000 persons treated)?

Pharco: The prices you showed will fall. Our prices will be falling by 2030. The prices will fall with volume. The \$80 is for a full 3-month treatment.

Question: You are a good example of success of local industry, which developed locally and made drugs to solve a major public health problem. What do you think about local industries emerging in neighboring countries? Do you see them as potential partners? Allies against multinational corporations? Or competitors?

Pharco: If you have a strategy to treat your people, and you can avoid the multinationals you should if your product is of quality and affordable. We manufacture the API and our price went down from 77,000 to 5,000 per kilo and then reduced it again. Multinationals can be powerful: we want to register daclatasvir in Saudi Arabia and the US ministry of trade asked the Saudi minister to come for a meeting. There, sofosbuvir is available, but for daclatasvir there is no generic and BMS product is registered. Saudi Arabia won't issue a CL. Generics companies together, if allied, can resist big Pharma pressures.

Question: Do you have any plans to produce HIV drugs?

Pharco: We are interested in producing API for DTG in either Egypt or Saudi but there is a patent issue. Like for sofosbuvir, we found a way to reduce the price. We won't do the same for DTG especially for Africa. In Geneva we have been asked to produce it, and we are currently doing a feasibility study and will start producing in the second quarter of 2018.

Question: We would like to ask some questions sent by our colleagues from ITPCru: Would you be willing to enter countries outside the Gilead license and MPP license where you're currently not present (Armenia first of all, where the government and civil society are in the process of developing the National Hepatitis Strategy)?

Pharco: Armenia is already covered by Gilead. We would be willing, but I don't know the IP situation there. I will check...

Question: Do you think that in case the Eurasian (or national in case of Moldova) patent for SOF is granted this could threaten your supplies?

Pharco: We have a process that is different from Gilead, this is patent 4 and 8, but if it's patent 1 and 2, then forget it. Before entering a country we need to know the patent situation. We are in the final registration steps for Moldova.

Question: Do you have any plans for introducing SOF/VEL in the countries of ITPCru region?

Pharco: Not yet. We are concentrating on sofosbuvir, daclatasvir and ravidasvir for now.

Meeting with BEKER



Beker Laboratoires is an Algerian company, specialized in the development, manufacturing, promotion and marketing of generic pharmaceutical products for various diseases. On hepatitis C, Becker produces different medicines, including sofosbuvir, daclatasvir, ledipasvir and ribavirin. Becker launched a new combo in November 2017, the fixed-dose combination of sofosbuvir/daclatasvir. Becker is not producing under voluntary licenses. (From presentation by Beker)

Pricing data presented by Beker:

Prices of Beker for Sofosbuvir/Ledipasvir:

	Price euro	Times	Total euros
SOF/LED	427 euros (\$532)		3 1,281euros (\$1597)
Diagnostic	150 euros (\$187)		3 450euros (\$561)
Genotype	150 euros (\$187)		1 150euros (\$187)
Total cure			1,881euros \$2345

Prices of Beker without diagnostics for Sofosbuvir/Daclatasvir:

	2000 patients	5000 patients	>10000 patients
Cost of the box/ one month	290euros (\$361)	261euros (\$325)	232euros (\$289)
Cost of the treatment without diagnostics	870euros (\$1,084)	783euros (\$976)	696euros (\$868)

Prices of Beker without diagnostics for Sofosbuvir/Ledipasvir:

	2000 patients	5000 patients	>10000 patients
Cost of the box/ one month	300euros (\$374)	270euros (\$336)	240euros (\$299)
Cost of the treatment without diagnostics	900euros (\$1122)	810euros (\$1010)	720euros (\$898)

Question: You just presented your products currently on the market. Do you have any others HCV or HBV in the pipeline?

Beker: For HBV, we are working on tenofovir. TDF/FTC is also in the pipeline. The availability of API is an issue. It's very expensive. We are developing this now, but we don't when it will be available. We are developing classical oncology products beyond HCV and HBV. We will be working on this over the next 2 years.

Question: Do you have any certifications related to good manufacturing processes and the quality of your products? Do you have any plan to apply to WHO pre-qualification or any other stringent authorities (US FDA, EMA)?

Beker: All the products we went through a quality control in Algeria. For other qualifications we have applied for WHO PQ. It's not only the documents we have to provide, but it is process. We presented our biological data for SOF last month and are preparing data for the SOF/DCV combination. We studied the combination SOF/DCV against SOF/LPV with 36 patients. The study was made public during the Hepatitis Summit in Sao Paulo. As for our bio-equivalence study, we did it in Jordan.

Question: Have you conducted any in-vivo bio-equivalence study ?

Beker: Yes, we have for all our HCV products.

Question: Do you have the intention of exporting? For which markets? We read your articles about your intention of exporting to France.

Beker: One of our goals is to export to rich countries where treatment is expensive. The drugs are very expensive. Switzerland did what we are recommending. In France, they refused.

Question: How do you explain the price difference between your products and Egyptian generics less than \$100 per cure?

Beker: In terms of quality of the API and the formula, and the bio-equivalence study; you will have differences in prices. We have the same quality as Gilead. You have countries that are strict on API, these conditions are strict, and I think we are the least expensive at this level. In Egypt you have economies of scale, there are millions of patients. You have quality, volumes and regulatory aspects. Maybe with expanding in Africa we can scale up and have an effect on the price. But I think we are the most affordable, the best value for money.

Question: Do you have any plans to produce HIV drugs especially that Algeria is excluded from VLs. Local production could be a solution?

Beker: We were focusing on Algeria. We don't have a high prevalence rate or burden. Beker is not working on HIV. Beker considers itself an African firm that is focused on new molecules. We market in Algeria.

Question: Given the current prices practiced by your potential competitors in India and Egypt for examples, do you have any plan or strategy to reduce your production cost and prices?

Beker: If we have 100,000 patients we can significantly reduce the price. These are long-term goals to create economy of scale and reduce prices.

Question: What is your profit margin on HCV drugs as compared to other medicines?

Beker: This is confidential. We cannot disclose this type of information. The more we increase our economies of scale. We have treated less than 5,000 patients. We are still trying to recover our investments in studies. So we cannot say we are making profits on these products. We are ending our bio-equivalence studies on daclatasvir. We have a margin of 25-30%. On HCV, all the work we did on SOF was for nothing.

Question: Where do you procure your API from? Is it quality-certified? What is the price per kilo for SOF for example?

Beker: I cannot answer publicly.

Question: Is there any other companies in Algeria with marketing approval for HCV drugs or in process of filing?

Beker: Under the Gilead license, Algeria was excluded. Then Gilead opened the access program to Algeria, Morocco and Tunisia and so, theoretically, we may have access to Indian generics.

Question: Can you speak about your online platform to sell HCV drugs? For whom it is destined and for what purpose, who are your clients? How do you guard against abuse, fraud? Who buys from this platform?

Beker: It is a challenge because of the issues you raised. If you go through the terms you will see lots of registration. We don't provide more than 3 boxes per person per prescription. We have a list of countries where personal use is allowed. We didn't sell to countries that didn't allow this because they could be stopped at customs. These aren't psychotropic drugs, these will still be used to treat HCV.

Question: What is your contribution to the Algerian National Strategic Plan?

Beker: It's a process. All the marketing, the tests are paid for by us. When there are national days of awareness-raising, we are engaged. We work with civil society, especially for testing. We produce films, rapid test.

Question: Do you have corporate social responsibility policy? Do you work with civil society in Algeria? Do you intend to work with civil society in the MENA region?

Beker: We have contact with CS around the world. We met some during the World Hepatitis Summit, as well as many stakeholders and people working on this issue. We hope to make more official partnerships including with HIV and co-infections. If there is a demand and that we have the capacity we will react.

CONCLUSION

The 2nd MENACAB meeting held in Marrakesh in November 2017 was an opportunity for MENA treatment advocates to build their capacities on drug development process and issues related to intellectual property; and to meet with Pharma companies to discuss access issues.

The meeting with ViiV Healthcare enabled to obtain a commitment from the company to extend its voluntary licenses on DTG to Jordan and any Lower middle-income countries. The company confirmed the possibility for countries excluded from the MPP voluntary licenses to be supplied by generics if there is no infringement of ViiV's patents. However, the company sticks to the exclusion of upper middle-income countries from licence territory including the exceptional case of Algeria. The only African country where to date generic supply is technically blocked by a granted patent. ViiV has not been able to provide details about its pricing policy in MENA countries and prefer case-by-case and country-by-country negotiations. However, the company expressed openness to work in the future with local activists to find solutions to improve access.

The meeting with the MPP was an opportunity for local advocates to better understand the organization's model and work. And for the MPP representative to meet in country advocates to better coordinate access strategies in the future. Both parts agreed on the necessity of continuous dialogue and information exchange to improve MPP licenses, their public health provisions and their territory.

The meetings with generics companies (Pharco, Pharma5 and Becker) allowed participants to realize the positive shift in domestic productions and the potential role that national companies can play in the response to the HCV epidemic. With the exception of Pharco, prices of locally made generic DAAs remain very high compared to lowest generics available and given the low cost of production. While, treatment acknowledged the role that volumes and market dynamics can play in pricing, efforts still need to be made by Pharma5 and Becker on pricing. Generics companies have also been asked, and committed, to be more proactive in their access policies, engage and support National Hepatitis Strategies beyond drug development. This includes raising awareness, testing campaigns and support to civil society.

ANNEXES

List of Community Participants

SOUFI SCANDER	Algeria
AHLEM AZZI	Algeria
FATMA ZAKI KHALED	Egypt
MOHAMED EL NASSER	Jordan
ELIE BALLAN	Lebanon
DIANA ABOU ABBAS	Lebanon
FATIMATA BALL	Mauritania
MORGANE AHMAR	Morocco
FATIMA ZAHRA SERGHINI	Morocco
ALIM EL GADDARI	Morocco
DETRICH PEELER	Morocco
AZIZ UR-REHMAN	Pakistan
SOUHAILA BENS Aid	Tunisia
FOUAD BOUTEMAK	Tunisia
OTHOMAN MELLOUK	Morocco
ALIA AMIMI	Morocco
MOHAMED ZNIBER	Morocco
ZAKARIA BAHTOUT	Morocco

List of representatives of Companies and Institutions

VIIV HEALTHCARE

HELEN MCDOWELL	Director, Government Affairs, Access an Patient Advocacy (Global)
ANJALI RADCLIFFE	Director, Policy, Community and Advocacy (International)
SIBONGILE KUBHEKA	Head of Medical Affairs, Middle East and Africa

MEDICINES PATENT POOL

ERIKA DUENAS	Policy and Advocacy Manager
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PHARMA5

MYRIAM LAHLOU-FILALI	General Director
YASMINE LAHLOU-FILALI	Vice President - General Director
KHADIJA RIHANE	Director of Research and Development

PHARCO

YASSER FAYED	Business Development Director
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BEKER

RACHID KERRAR	General Director
ISMAHANE BENBITOUR	Business Development and Project Management Director

Notes:

