Diagnosis and monitoring of hepatitis C (HCV) in Morocco

Current Status and strategies for universal access

Benchmarking HCV diagnostics, fibrosis evaluation, and treatment monitoring

Pauline Londeix, May 2018
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Since its launch in 1988, the Association de Lutte Contre le Sida (ALCS), the first organization of its kind in the MENA region, has pursued as aims the prevention of HIV infection and viral hepatitis, with particular emphasis on the most vulnerable populations, access to treatment, and the promotion of rights for people living with HIV. ALCS played a key role in the introduction of access to antiretroviral therapies in Morocco as in 1998, in the scale up of coverage, in advocacy for access to generics, as well as in the reduction of prices of new medicines, diagnostics and follow-up tools. ALCS is a founding member of Coalition Plus, an international coalition of community-based organizations in thirteen countries (Bolivia, Burkina Faso, Burundi, Canada, Congo (DR), Equator, France, Mali, Mauritius, Morocco, Portugal, Roumania and Switzerland). Its main objective consists in the promotion of a community-led approach in the fight against HIV/AIDS. To advance this objective, Coalition PLUS has engaged in capacity strengthening programs, advocacy activities, and a community-focused research program.

Since 2014, ALCS has implemented several actions aiming for the universal access to care for Hepatitis C in Morocco. Since September 2016, these activities have been structured in the framework of of a project funded by Unitaid. It is within the framework of this program that this report is released.

Disclaimer:
The author of this report made the utmost effort to assure the accuracy of the information in this report, most of which was provided by various stakeholders interviewed during the research for this report. However, this document does not claim a comprehensive accuracy, as it is snapshot of conditions at the time of the research process. The document aims to provide insights on the issue of diagnostics and follow-up tools for HCV infection, an issue with limited documentation by the international community at present.

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EXECUTIVE SUMMARY

REPORT CONTEXT

In 2017, the World Health Organization estimated that nearly 71 million people worldwide were living with chronic Hepatitis C Virus infection. Untreated, chronic HCV causes liver fibrosis which can progress to cirrhosis or carcinoma.

In Morocco, an estimated 1.2% of the general population, about 400,000 people, are living with HCV. At the end of 2018, the Ministry of Health will announce a five-year National Strategic Plan (NSP) for viral hepatitis that aims to eliminate HCV by 2030.

In 2013, the arrival of Direct-Acting Antivirals (DAAs) was a turning point in the history of the epidemic. DAAs, which offer excellent therapeutic results, have become standard care in most countries with a national viral hepatitis program.

International community pressure has led to accelerated market access for generic versions of DAAs in a number of resource-limited countries. In Morocco, in the absence of patents granted for sofosbuvir and daclatasvir, Moroccan companies were able to introduce generic versions at prices at far below those set by the originator companies. In late 2017, two Moroccan firms were offering dual therapy sofosbuvir+daclatasvir for $1,400.

If the issue of treatment price is crucial, the issue of the availability and costs of screening, diagnostics, and monitoring tools against HCV infection are also essential to identifying people living with HCV and to selecting therapeutic strategies which ultimately ensure successful treatment.

The objective of this report is to assess the availability of the above-mentioned tools and tests as of late 2017, on the eve of the official launch of the NSP by the Ministry of Health (MoH). It also aims to identify strategies and opportunities to expand and improve access to diagnostics.
KEY OBSERVATIONS

Availability of tests, decentralization and national recommendations

Screening

In Morocco, following positive HCV serology, the national program against viral hepatitis recommends a viral load test. If chronic infection is confirmed by viral load, further tests will be needed. Several rapid tests for HCV have been registered in Morocco. They are still little used, except in specific cases. A directive pertaining to their widespread use has not yet been issued. However, a competitive call to tender has been opened to several suppliers. Initial HCV screening is serological and available in national laboratories, blood transfusion centers, University Hospitals (CHU), but rarely in Provincial Hospitals Centers (CHP) or Regional Hospitals (CHR).

Viral load

HCV viral load diagnosis, required to confirm chronic HCV, is available in Morocco at the tertiary level, as is the viral load measured after the treatment to assess therapeutic success. On the basis of samples of plasma or dried blood spots (DBS), viral load analysis occurs in two steps: first nucleic acid extraction, secondly amplification and quantification.

Different reagents are required for each of these phases. Provided the laboratory where the sample was taken is equipped with a centrifuge and the sample is kept in good conditions, it may be transported over long distances to labs with extraction and amplification-quantification platforms.

Genotyping

Because of the pan-genotypic activity of new DAAAs, genotype testing is no longer a systematic requirement. The Ministry of Health aims to equip 6 centers across Morocco at long term. To avoid making patients travel too far from their usual specialist centers, samples are taken at specialist centers and sent to one of six centers able to perform genotyping, with results available one to two weeks later according to estimates.

Fibrosis and liver diseases evaluation

WHO recommends assessing fibrosis primarily with non-invasive methods such as ActiTest® or FibroTest® (specific biological test) and FibroScan® (Transient Elastography).

In Morocco, FibroTest® is available at the Institut Pasteur du Maroc (IPM) in Casablanca, among others. The laboratory offers BioPredictive FibroTest® in a large majority of private laboratories unequally distributed across
Moroccan territory. FibroScan® devices, meanwhile, are available in the cities of Casablanca, Rabat and Oujda. According to the MoH, ten FibroScan® are being acquired for regional hospitals.

Decentralization and care distribution

Currently, more than 20 provincial and regional specialised centers are involved in HCV management. The NSP aims for services at 23 specialist centers and 5 University Hospitals. The lack of FibroScan® and structures able to perform ActiTest®/FibroTest® means long and expensive trips for all the people from the south and east of the country towards the specialised centers. For those farthest from existing health care facilities, traveling the length of the country for their test might be prohibitively expensive and lead to loss-to-follow-up of these patients.

Medical coverage

At year’s end 2016, 28% of Moroccans were enrolled in the RAMED Medical Assistance Plan. Beneficiaries are therefore entitled to free access to diagnostics and follow-up. Again at year’s end 2016, 34% of Moroccans were enrolled in the Mandatory Health Insurance (AMO) and its two funds CNSS and CNOPS. Despite reimbursement of patient expenditures that cover a minimum of 80%, the patient still has to pay out of pocket the remaining part. At year’s end 2016, an estimated 35% of the population had no health insurance at all.

Enrolled or not, patients must cover fully or partially the cost of the tests which range from $400 to $520, while monthly gross national income per capita is only at $245. These figures do not take into account expenses related to transportation, accommodation, medical appointments, ancillary costs, and lost opportunity costs borne by people living with HCV. Tests conducted in the private sector may be partially reimbursed for beneficiaries of private insurance or AMO, but those individuals without health insurance must bear the full cost.

Prices paid by the Moroccan State: analysis

Procurement Procedures in Morocco

The Directorate of Epidemiology and Diseases Control (DELM) is in charge of procurement, issuing tenders, placing orders and managing inventory planning. As part of the programs financed by the Global Fund against AIDS, Tuberculosis and Malaria (GFATM) and its HIV targeted programs, the purchase of antiretroviral drugs, diagnostics platforms and reagents is now handled by the Pooled Procurement Mechanism (PPM), and specifically through the IDA Foundation. Given the large volumes, bulk purchases allow countries access, frequently but not always, to lower prices for antiretroviral drugs and other health
products than otherwise possible. The PPM will be replaced by a purchasing platform called Wambo, which could be made available for countries beyond the Global Fund programs. Morocco has therefore launched a ‘classic’ call to tender for rapid HCV tests, as well as for diagnostic platforms to perform HCV viral load tests and the required reagents. Some platforms, financed by the Global Fund, have been used, in agreement with the Global Fund, to perform laboratory tests other than HIV, including HCV.

**HCV viral load testing**

Abbott, Roche and Cepheid benefit from a near-monopoly of platforms used in Morocco to measure HIV and HCV viral loads. Although large volumes sometimes translate into discounts, these remain marginal. According to the Ministry of Health, HCV and HIV viral loads will be available at MAD 155 ($17) and MAD 170 ($18) after the acquisition of Genexpert Cepheid platforms in 2018. As part of the Global Fund program, Roche offers the HIV viral load at a price of $9.40 (excluding maintenance and the cost of the platform). Yet, despite Morocco being one of the countries eligible for this program, at year’s end 2017, Morocco was still paying Roche $20 per viral load test performed. Abbott offers discounted rates for fixed term commitments. Under such discounts, the regular $25 per test for viral load HIV can drop to $13 (excluding the price of the platform and annual maintenance). Morocco is also part of the Cepheid program, which provides HIV viral load tests at $15. The Moroccan public sector therefore has access only to ‘closed’, proprietary platforms. Morocco does not have Biocentric type platforms, which are open and polyvalent, that is to say open to reagents and components of different brands, and therefore potentially cheaper due to more competition. Biocentric unitary viral load tests currently stand at $15. Regarding intellectual property pertaining to HIV viral load testing, most of the patents on these products or processes, which had been filed by Abbott, Roche, Qiagen, Siemens, bioMérieux, and Life Technologies, among others, have expired.

**Platforms for the non-invasive assessment of liver fibrosis**

Compared to other instruments for the assessment of liver fibrosis by non-invasive methods, FibroScan® marketed by Echosens, operates without reagent, which is a major asset, although the unit requires several maintenance sessions each year. Moreover, it is noteworthy that a ‘mini FibroScan®’ was developed for field use. As for the FibroTest®/ActiTest®, it is based on a blood test that is invoiced to the tests results analysis holder, BioPredictive. This is the major drawback of this technology as the manufacturer can set prices unilaterally. BioPredictive invoices between $59 and $88 per unit to a variety of countries. The FibroScan® and FibroTest® technologies have enjoyed significant commercial success, access. It is important to note that FibroScan® and FibroTest® technologies were derived from publicly-funded French research. FibroScan® was invented and developed by researchers who received public funding that originated at the National Institutes of Health and Research (INSERM) and the Graduate School of Industrial Physics and Chemistry the city of Paris (ESPCI). The FibroTest® is also derived from publicly-funded French research; notably, it was initially designed and developed by AP-HP (Assistance Publique-Hôpitaux de Paris). AP-HP, BioPredictive and INSERM have developed and patented the invention. BioPredictive today is the only one to use this technology, and outsources its marketing in the US market to LabCorp.
HCV diagnostics price, comparative study

General comments

This comparative study refers to the rates and prices for serology, rapid tests, viral load, genotyping and FibroScan® or FibroTest® testing for HCV in nineteen other middle-income countries. The limitation of this study lies in the significant differences between health systems, where prices do not necessarily reflect what is actually paid by states. Not all countries in the comparative study have rapid tests yet, but where they are brought to market, the average price was about $1. Regarding conventional serological tests, prices rarely exceed $10 in the public sector. For viral load, the lowest prices are those of Egypt ($14) and Brazil ($18). If the price of reagents is slightly declining, bulk purchases have not had any significant impact on prices. The number of countries using Abbott and Roche equipment is quite significant. As for genotyping, it is not available everywhere. In general, Egypt appears to have the lowest prices, followed by Tunisia and Ukraine. As for FibroTest®, price is high in all countries where it is available, never less than $50. FibroScan® is mainly available in capital cities, and the cost can be reduced for those enrolled in national health insurance schemes. In general, tests are performed mainly in large cities. Social coverage systems vary from one country to another, as illustrated by the examples of Morocco, Brazil, Ukraine, Georgia and Vietnam.

Morocco compared to other MENA/EMRO countries

This comparative study covers seven MENA/EMRO countries. In terms of average gross wage per capita, Morocco is ahead only of lowest-ranking Pakistan. Average salaries or wages provide a good yardstick to measure patient’s actual health expenditure. Noticeably, Morocco and Pakistan are the two countries in the MENA/EMRO region where diagnostics spending ratio to salary or wages is the highest. In Morocco, diagnosis costs stand at twice the monthly gross national revenue per capita.

Legal environment: overview

Under Moroccan law, the main sources of jurisdiction are the Constitution, Royal Decrees and the laws passed by Parliament. Morocco’s Constitution of 2011 reaffirms the right to health as a fundamental right, the right to ‘social protection, medical insurance and to solidarity mutualized or organized by the state. Laws and decrees govern the health system and the implementation of decentralization, registration of drugs and reagents in Morocco, prices and public procurement, competition and intellectual property rights.

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1World Health Organization East Mediterranean Regional Office
Key recommendations:

- To immediately launch the 2017-2022 National Strategic Plan including screening campaigns and implement cost free access regardless of patients social insurance coverage.

- Effective establishment of HCV specialised referral care centers across Morocco.

- The consultation of different stakeholders to optimally coordinate national policy for diagnostic tests procurement and to mutualise platforms for viral load tests, as well as related reagent supplies, human resources, and sample collection & transport.

- A full utilization of Roche price through the Global Fund's PPM for HIV viral load ($9.40), and an attempt to renegotiate the price with Roche for the HCV viral load test with HIV as reference price.

- Widen the scope of the Global Fund's pooled procurement platform, Wambo, to provide low and middle income countries with a new option as regards to reagents purchasing.

- The use the most systematically as possible of open platforms for viral load measurement (HIV, HCV and HBV), which will trigger competition and can be used as leverage in price renegotiations with Abbott, Roche and Cepheid for the equipments already acquired by the public moroccan structures.

- The implementation of a strategy in regards to the purchase of reagents as well as for the raw material for the reagents, in the order to reduce more the manufacturing costs of reagents for producers and to reduce prices.

- The introduction and development of local production platforms, reagents and raw material for reagents, for viral load tests based on public health needs in the country in order to obtain lower prices and limit dependency on a few companies in a position of monopolies and are thus able to set prices almost unilaterally.

- The launch of a South-South cooperation strategy, with Brazil for example, which has an interesting track record in fostering local production of healthcare products, including diagnostics.

- Gather the public sector, private sector, and civil society to reflect on opportunities for technology transfer, particularly for patented technologies, such as non-invasive fibrosis evaluation methods.

- As for the viral load, the expiration of most the patents on these technologies, confirms that the less relevant strategy for local producers might be the resort to technology transfers, as those tie originator and patent holder producers to the other producers willing to produce these technologies, thus expending their monopoly beyond the patent term. By itself, the expiration of patents should allow any producer willing to do so to develop the technologies, either thanks to the disclosed information in the patent application, or by reverse engineering.

- Expand access to FibroTest® and end BioPredictive’s monopoly which has a direct impact on people’s access to it. Assistance Publique des Hôpitaux de Paris (AP-HP) and INSERM should cancel the exclusive marketing license granted to BioPredictive, and instead grant open licenses, including to Moroccan producers, and offer them technology transfers. The resort to open licenses in such cases has been recommended in the report of the high level panel on essential medicines to the United Nations Secretary general in September 2016.

- Expand access to FibroScan® and end the monopoly of Echosens, INSERM, INSERM Transfert and ESPCI who must position themselves in favor of open licenses for and technology transfers to countries and private or public stakeholders who need them.

- Finally, in order to reduce the negative impact of intellectual property on access to medicines and technologies for health, the ALECA agreement currently being negotiated between the EU and Morocco should be abandoned.
INTRODUCTION
INTRODUCTION

Hepatitis C is a liver disease caused by the Hepatitis C Virus (HCV). In 2017, the World Health Organization estimates that nearly 71 million people worldwide are living with chronic HCV infection. Untreated, chronic HCV causes the development of liver fibrosis progressing to cirrhosis or carcinoma. HCV has a high genetic variability, with more than 6 genotypes identified worldwide.

Until 2013, the peg-interferon plus ribavirin combination therapy was the standard of care. Unfortunately this treatment has major side effects and significant failure rates.

In 2013, the arrival of direct-acting antivirals (DAAs) was a turning point in the history of HCV epidemic. Since then DAAs have become standard care in most countries with an established a national viral hepatitis response program. DAAs offer very good therapeutic results, with excellent sustained virologic response (SVR) rates at treatment’s end. The most commonly used DAAs are sofosbuvir, ledipasvir and daclatasvir.

Between 2013 and 2015, ‘standardized’ yet highly prohibitive prices were imposed by pharmaceutical companies holding intellectual property rights to these molecules (notably Gilead and Bristol Myers Squibb (BMS)) thereby placing a serious obstacle to access these medicines for a very large number of people. However, pressure from the international community has provided accelerated market access for generic versions of these drugs in a number of resource-limited countries. From $84,000 in the US in 2014, sofosbuvir dropped to $900 in Egypt in 2015. The non-governmental organization (NGO) Médecins Sans Frontières (MSF) stated in late October 2017 that they had negotiated an agreement for the provision of a 3 month sofosbuvir and daclatasvir combination treatment at $120 for 11 low and middle income countries.

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3 WHO Hepatitis C Fact sheet, Updated October 2017 http://www.who.int/mediacentre/factsheets/fs164/fr/

4 HCV is, in some cases, naturally eliminated by the body. Otherwise it is known as a ‘chronic infection.

5 Huffingtonpost.com « The Drug That Is Bankrupting America » https://www.huffingtonpost.com/jeffrey-sachs/the-drug-that-is-bankrupt_b_6692340.html

In Morocco, the absence of granted patents on sofosbuvir and daclatasvir allows Moroccan companies to provide generic versions at prices radically lower than those of Gilead and BMS. Local firms, Pharma 5 and Galenica were offering dual sofosbuvir/daclatasvir therapy priced at $1,400⁷. Compared to the initial price requested by the originators Gilead and BMS, the difference is dramatic and makes broad treatment realistically achievable in Morocco, in line with National Strategic Plan objectives and essential to Morocco’s stated objective of HCV elimination by 2030.

Despite local production of the new DAAs, these are not currently available in the public sector, due to an existing stock of peg-interferon and delays in the launch of the NSP. But the price of DAAs is not the only barrier to access to care. Tools for screening, diagnosis, and monitoring of HCV infection are both essential to identifying people living with HCV, identifying therapeutic strategies and ultimately to ensuring successful treatment.

In October 2017, Dr. Andrew Hill of the University of Liverpool published a study⁸ on the issue of screening. Worldwide, only 20% of people chronically living with HCV have been detected. Increased screening is crucial. Similar conditions prevail for all pre-treatment tests recommended by the World Health Organization: genotyping tests in some cases, viral load tests and hepatic fibrosis evaluation.

The objective of this report is to assess the availability of these tools and tests as of early 2018, on the eve of the official launch of the NSP by the MoH. It also aims to try to identify potential strategies and opportunities to expand and optimize access to diagnostics.

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⁷ Pharma5 and Galenica have registered on the moroccan market generics for sofosbuvir at a price of $900 for 12 weeks of treatment http://medicament.ma/medicament/sob-400-comprime/ and Pharma5 and Galenica, daclatasvir for less than $500 for 12 weeks. http://medicament.ma/medicament/daksvir-60mg/; Mylan has marketed a generic version of a fixed dose combination sofosbuvir/ledipasvir.

⁸ Hill Andrew « Diagnostic Burn-out” for Hepatitis C: when will countries run out of diagnosed people to treat with DAAs? », Liverpool University, October 2017
BENCHMARK OBJECTIVES

This report aims to assess diagnostic tests and monitoring of HCV infection, review liver fibrosis assessment procedures in Morocco in terms of availability, to document access and prices of these tests in Morocco against other countries in the region and others at the same socioeconomic level as per World Bank criteria.

This report is first and foremost a snapshot, aiming to bring insights on the issue of diagnostics and follow-up tools for HCV infection.

GENERAL METHODOLOGY

Interviews were conducted in September 2017 in Rabat with key actors of the national response to viral hepatitis in Morocco, namely Pr. Abderrahmane Maaroufi, director of Epidemiology and Diseases Control Department (DELM), Dr. Ibtisam Khoudri, national coordinator for the viral hepatitis response program, as well as Dr. Hicham Oumzil, from the National Institute of Hygiene (INH).

A meeting was held in October 2017 at the Pasteur Institute of Morocco (IPM) with Dr. Lahcen Wakrim, Head of virology-Immunovirology, Research Department and HIV specialist, and with Dr. Ezzikouri, Viral Hepatitis Service, Medical Biology Department, and Head of Communicable Diseases Diagnostics Division (Medical Biology Department).

Discussion were also held with Myriam Lahlou-Filali, Yasmine Lahlou-Filali and Khadija Rihane (Pharma5), Isabelle Andrieux-Meyer (DNDi), Jean-Marie Castille (BioPredictive), Emmanuel Fajardo (Doctors Without Borders-MSF), Sophie Ouvrard (Solthis/Project OPP-ERA9), Laurent Sandrin (Echosens), Marc Tordjeman (Biocentric), Mickael Tanter (INSERM/ESPCI) and Koichi Kameda Carvalho, a PhD student at the EHESS and diagnostics and local production specialist10.

For readability, this report presents all the rates and prices in US dollars ($), and rounded to the nearest unit.

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9 Project led by a consortium of Solthis, Sidaction, ANRS to improve access to HIV viral load tests in many Francophone Sub-Saharan countries

ORGANIZATION OF THE HEALTH SYSTEM IN MOROCCO

Morocco is a country in North Africa with a population of 33.8 million. Morocco is defined by the World Bank as a “lower middle income country” (LMIC) and its nominal gross domestic product (GDP) per capita in 2013 was about $3575 (113th in the ranking). The poverty rate stands at about 5% and unemployment is relatively high at about 10%. The average salary is estimated at about $500.¹¹

Morocco is in the MENA region (North Africa/Middle East) and included in WHO-EMRO for the World Health Organization’s Eastern Mediterranean Regional Office.

Life expectancy at birth in 2012 was 74.8 years. Nearly 60% of the population lives in urban areas. In the Human Development Index (HDI), Morocco was ranked 123rd in 2016.

Health care in Morocco is provided by both public and private structures.

According to the MoH, the public health sector has 2689 primary health care facilities, 144 hospitals (at different levels: local, provincial, regional and tertiary) and about 22,146 beds. The private sector is made of 6763 private practices and 439 clinics, located primarily in urban areas and on the North Atlantic coast.

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¹¹ Morocco’s Disposable Income Among the Lowest in The World ➞
https://www.moroccoworldnews.com/2015/03/155126/moroccos-disposable-income-among-lowest-world/
Health costs in Morocco are partially covered by two basic plans: AMO and RAMED. The Mandatory Health Insurance (AMO) for private and public sector employees covers 34% of the population. AMO is based on the principle of risk pooling and financial contribution of the beneficiaries (and employers). If it covers much of the costs, it leaves some of the costs to the beneficiaries.

At year’s end 2016, 35% of the general population remained not covered by social protection schemes.

The Medical Assistance Plan (RAMED) covers, meanwhile, 28% of the population, about 8.5 million Moroccans, and covers the most needy. It is funded by the state and local authorities. Private insurance covers about 5% of the population. Medical coverage was extended to students in 2016 and must also be extended to independents to ensure universal access for the entire population. At year’s end 2016, 35% of the general population remained not covered by social protection schemes.

One of the eligibility criteria for RAMED for people living in urban areas is to have an annual income below 5,650 DH ($596) or about $50 per month. Beyond this income, RAMED membership is compromised.

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\textsuperscript{12} RAMED eligibility criteria https://www.ramed.ma/SInformer/Pages/ConditionsAdhesion.html
Epidemiological context of HCV in Morocco

An estimated 1.2% of the Moroccan general population is living with HCV, placing Morocco among the countries of 'intermediate endemicity' by WHO and the Center for Disease Control (CDC) standards.

Other studies using systematic sampling confirmed prevalence between 1 and 2% of the general population. Infection was mainly associated with advanced age, dental care, the use of glass syringes, and a history of surgery. Prevalence is the strongest among injected drug users (IDUs), especially in the north of Morocco. A study by the MoH showed prevalence in this population to stand at 45% in Tangier and 79% in Nador. Other populations where the prevalence is particularly high are those living with hemodialysis (35 to 76%), hemophiliacs, people living with HIV or Sexually Transmitted Disease (STD) carriers, people who stayed in hospital and barbershop customers.

As estimated by the MoH, the predominant genotypes are genotypes 1 (56%) and 2 (42%). Genotype 3 is present but rare (2%).

At year’s end 2017, no systematic prevalence study had been carried out at national level.

At year’s end 2017, no systematic prevalence study had been carried out at national level.

Beginning 2018, the Ministry of Health will announce a five year National Strategic Plan addressing viral hepatitis. Priority will be given to the HCV response. The objectives of this plan are ambitious and aim in particular to eliminate the disease by 2030.
PART 1

HCV INFECTION DIAGNOSTIC AND MONITORING TOOLS IN MOROCCO
In Morocco, after positive HCV serology (enzyme-linked immunosorbent antibodies assay), the national program against viral hepatitis recommends conducting a viral load test. Then, if chronic infection is confirmed by viral load, more tests are required. The genotype must be determined to adapt treatment protocol if pan-genotypic treatments are not available.

As of November 2017, genotyping is no longer mandatory for all people living with HCV in Morocco except for those individuals with cirrhosis, or those who are not treatment naïve for whom treatment may need to be extended. Treatment can be adapted, for example with a longer treatment than the standard one.

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Table: HCV infection diagnostic tests and monitoring in Morocco
A large proportion of people with hepatitis C is detected at symptomatic stages of HCV infection as it can remain asymptomatic for many years. At this stage, damage to the liver is often substantial. Therefore, it is essential to conduct screening strategies to identify people before symptoms appear and prevent the development of liver fibrosis. WHO recommends targeted screening especially for key populations, such as IDUs and those already living with HBV and/or HIV. In the United States, a policy of screening also based on demographic criteria, taking particular account of age, has been set up. And, to better target the populations to be screened, WHO recommends countries assess as precisely as possible the specifics of their epidemic, particularly through nationwide prevalence studies. In the US and Western Europe, HCV screening is routinely recommended for people living with HIV.

In many countries, conventional HCV serology is replaced or supplemented by rapid tests which provide almost immediate results, without requiring a blood sample in a medical setting. Despite rapid tests providing many false accurates, and despite being slightly less reliable than traditional serology, they have many benefits. They can be easily performed in remote areas away from care structures. In Morocco, several rapid tests have been registered by the Directorate of drugs and pharmaceuticals (DMP), including SD Bioline, pre-qualified by WHO (see image below), but they are still not widely used, except in certain settings for key populations such as IDUs or People living with HIV/AIDS (PLWHA). The directive allowing their widespread use has not yet been issued. However, a competitive call to tender has been sent to several producers to compete for the provision of tests.

As stated by the NSP 2017-2021 itself, ‘The number of screenings performed annually is not known precisely and ‘PHC and RHC laboratory capacity in terms of detection and diagnosis of HCV is limited.’

HCV screening is conducted via a serological test. It is available in national laboratories, transfusion centers, CHUs (University Hospitals), but seldom at the secondary level of Provincial Hospital centers (CHP) and Regional Hospital centers (CHR). At year’s end 2017, screenings is not systematic for pregnant women. As stated by the NSP 2017-2021 itself, ‘The number of screenings performed annually is not known precisely’, and ‘PHC and RHC laboratory capacity in terms of detection and diagnosis of HCV is limited.’

Photo: Example of a HCV rapid test registered in Morocco
Unlike HIV, new HCV cases are not subject to a mandatory declaration. For HIV, this measure helped refine epidemiological data and adapt national response.\(^{13}\) It might be considered regrettable that the system does not allow the voluntary registration of new cases, whether or not it were compulsory as is the case for HIV. It might also be considered regrettable that a system fails to make the connection between certain liver diseases, including cirrhosis and liver cancer and the possible viral hepatitis cause.

**NSP 2017-2021 screening provisions**

Through this NSP, the Ministry of Health (MoH) intends to provide key and vulnerable populations ‘gradually given population size, [with] access to HCV prevention, screening and care.’ The MoH also plans to integrate HCV screening activities within the network of basic health care facilities and the national system dedicated to HIV, in a decentralized manner. ‘Active’ screening will be carried out in facilities which already support target groups living with HIV. ‘Passive’ HCV screening will be realized in healthcare facilities, public and private institutions, basic health care facilities, CHP, CHR and CHU. It will also be available at health centers already equipped with HIV tests. CHP and CHR will have priority access to rapid tests during this period.

To achieve these objectives, the MoH aims to ‘strengthen chronic HCV diagnostic capabilities and foster innovative quality methods to facilitate access to screening’. Screening will be carried out by medical staff, general practitioners or specialists, or suitably trained paramedical staff.

The participation of NGOs in screening, particularly for key populations, is already acquired.

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\(^{13}\) In France, declaring HCV infections is also not a requirement, unlike HIV or symptomatic HBV.
Hepatitis C serology enables, through assaying anti-hepatitis C antibodies, the detection of HCV infection. But viral load confirmation is still required to distinguish those who have already naturally cleared the virus from those in whom the infection has become chronic.

**Performing this viral load test after the first positive screening is therefore necessary to determine a person’s serological status.**

In practice, assessing the viral load requires a two-stage process: first comes nucleic acid extraction, then amplification and quantification, with a reagent required for each.

Analysis is performed from a plasma sample, or, alternatively, on samples collected on blotting paper. Provided the laboratory where the sample was taken is equipped with a centrifuge and the sample is kept in good conditions, it may be transported over long distances to venues hosting extraction and amplification-quantification platforms.

**Provided the laboratory where the sample was taken is equipped with a centrifuge and the sample is kept in good conditions, it may be transported over long distances.**

At room temperature, plasma can only be kept 24 hours. On the other hand, at 4°C (40°F) it can be kept for 5 days, which leaves enough time for it to reach laboratories equipped with the technology to carry out these tests.
EVALUATION OF FIBROSIS AND LIVER DISEASES

There are several methods for assessing fibrosis and liver diseases. Percutaneous Liver Biopsy is one of the oldest, but has its limitations as it is performed under local or general anesthesia with all the risks these entail, and it can also lead to complications and bleeding problems. It requires a hospital stay of a few hours and is practiced by hepatologists, and is often quite expensive.

For all these reasons, the advent of non-invasive methods for fibrosis assessment represented a very important step forward. WHO also recommends assessing the progress of fibrosis with non-invasive methods before starting treatment. WHO considers that from stage 2 fibrosis (F2) to cirrhosis stage, an immediate start to treatment is required.

FibroScan® offers the advantage of not requiring reagents, which can limit their prices, but forcing people to move to places equipped with the required equipment.
Two main methods for assessing fibrosis exist. WHO\textsuperscript{14} recommends using ActiTest®-FibroTest® (specific biological test) and FibroScan® (a transient elastography method). FibroScan® offers the advantage of not requiring reagents, which can limit their prices, but forcing people to move to places equipped with the required equipment. The FibroScan® test is a technique that allows to determine two parameters in the liver without penetrating inside the human body, namely liver hardness and ultrasonic attenuation.

As for the FibroTest, it is available at IPM Casablanca, including laboratory and BioPredictive sells it in different laboratories (8 laboratories in Rabat, 33 in Casablanca, 1 in Témara, Fez, Marrakech, Meknes, Tangier and Tetouan respectively), in a large majority of private laboratories but remains very clearly unequally distributed across the Kingdom.

In both cases, these tests are forcing all the people of the south and east of the country to take long and expensive trips. In the absence of regional hospitals in the region of Ouarzazate (Eastern Morocco), Laayoune or Dakhla (both in Morocco's far south), people living there with HCV have to travel long distances to Marrakech or Agadir for their tests.

For reasons of cost and availability of materials, the WHO recommends that countries with limited resources use the APRI (aminotransferase/platelet ratio index) or FIB-4 test in all centers that cannot be equipped with FibroTest®. However, FibroTest® and elastography tests offer more precise measurements and must resources allowing, therefore be given priority (the APRI and FIB-4 scores also carry the risk of obtaining false negative or false positive). Furthermore, there are also 'mini' portable Fibroscan® easily adapted to mobile screening campaigns.

\textbf{Map : Geographic distribution of liver assessment equipment (FibroTest® and Fibroscan®) in Morocco, 2017}

\textsuperscript{14} WHO also recommends liver exams (invasive) but considers non-invasive procedures preferable.
GENOTYPING

WHO recommends genotyping tests in countries where at least two different genotypes predominate, which is the case in Morocco. However, the generalization of 'pan-genotypic' treatment as sofosbuvir and daclatasvir should make this test unnecessary. WHO continues to consider this an important test. Nonetheless, when genotyping is not available or too expensive, it is recommended to act pragmatically and to apply the treatment used for the predominant genotype.

The cost of genotyping test is borne, at least in part, by all those not covered by RAMED.

The simplification of the protocol was acted early November 2017 and aims to simplify processes and avoid patients being lost to follow-up between HCV diagnosis and treatment initiation. Indeed, the cost of genotyping test is borne, at least in part, by all those not covered by RAMED. Moreover, this test requires of the patient an extra trip to their referring center.

Genotyping remains mandatory for all non treatment-naive individuals or those with decompensated cirrhosis because treatment protocol can be adapted to their situation.

The MoH wishes that eventually genotyping will be possible in 6 centers in Morocco. And so that people do not have to travel, samples are taken from the reference centers and sent to one of six centers able to perform genotyping. The turnaround time estimated by the MoH to obtain the results is one to two weeks.

MONITORING DURING TREATMENT

WHO recommends a total of two viral load tests, one immediately after positive serology, the second a few weeks after the end of treatment. The first, before starting treatment, upon confirmation of the infection, and the second at week 24 from the end of treatment. Until recently, 4 viral loads were recommended, but in November 2017 DELM decided to simplify the protocol, and reduce it to two. This simplification represents a real advance for patients as they will not have to travel or front substantial sums of money to access treatment before being partially reimbursed by their insurance.
Attending physicians may prescribe the test, but only gastroenterologists are authorized to prescribe treatment.

In 2012, the care of people living with HCV was limited to seven centers called 'regional centers of excellence.' Currently, according to the MoH, more than 20 provincial and regional reference centers contribute to HCV management. These are the 23 reference centers and 5 CHU which will be implemented after the launch of the PSN. Attending physicians may prescribe the test, but only gastroenterologists are authorized to prescribe treatment. There are 800 gastroenterologists in Morocco.\(^{15}\)

\(^{15}\) Against, for example, 30 infectiologists.
Reference centers for HCV support will be many, even if they appear to be insufficient numbers in the east, south and southeast of the country.

As illustrated in the map above, reference centers for HCV support will be many, even if they appear to be insufficient numbers in the east, south and southeast of the country, particularly in the region of Ouarzazate, which depends on the center of Marrakech, or in the South (Laayoune, Dakhla). For example, the inhabitants of this region have to go to Marrakech for health treatment in the public sector, which can be expensive and very long (at least a 10 hour - round trip). They can also go to private laboratories if they are equipped, but they will be reimbursed unequally.

THE EXAMPLE OF THE PASTEUR INSTITUTE OF MOROCCO (IPM), CASABLANCA

**SEROLOGY**: At IPM, located in Casablanca, rapid tests are not yet used. Only serology (chemiluminescence for HCV detection) is used as a screening test. Sometimes people arrive following a positive rapid test to perform serology. After the positive status, the person must return to see their doctor before returning to IPM to establish viral load and, if positive, genotyping (until early November 2017, for all people who test positive).

**VIRAL LOAD**: At IPM, assays are performed on site. The person returns to their doctor between viral load and genotyping.

**GENOTYPING**: is performed at IPM. If the doctor prescribes it, genotyping and FibroTest® can be performed simultaneously, but patients must come to IPM for all FibroTest®/ActiTest® assays.

THE CASE OF NATIONAL HYGIENE INSTITUTE (INH), RABAT

Rapid tests, serological tests and evaluation of fibrosis are not conducted at INH, but viral load and genotyping are. Samples received from regional hospitals. In the wider Rabat region, people come to INH.

People are addressed directly by the gastroenterologists of the public sector of the Oriental region, Tangier, Tetouan, Rabat, Salé, Housseima, Nador, Fez, Meknes, Marrakesh, Casablanca and Beni Mellal.
PART 2

ANALYSIS OF PRICES PAID BY INDIVIDUALS AND BY THE MOROCCAN STATE
## Analysis of prices paid by individuals and by the Moroccan State

By the end of 2016, 28% of Moroccans availed in RAMED, a medical assistance schema for the most indigent who benefit from an all free healthcare, except for the viral load for cock they have to pay for the reagent.

<table>
<thead>
<tr>
<th></th>
<th>Serology</th>
<th>viral load 1</th>
<th>Genotyping</th>
<th>Fibrotest®</th>
<th>viral load 2</th>
<th>Total cost for the patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAMED beneficiaries</td>
<td>$0 (0dh)</td>
<td>$0 (0dh)</td>
<td>$0 (0dh)</td>
<td>$0 (0dh)</td>
<td>$0 (0dh)</td>
<td>$0 (0dh) excludes transport and ancillary exams.</td>
</tr>
<tr>
<td>CNSS beneficiaries</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(private formal sector)</td>
<td>$31.5 (300dh) partially refunded</td>
<td>$121 (1150dh) partially refunded</td>
<td>$121 (1150dh) partially refunded</td>
<td>$126 (1200dh) partially refunded</td>
<td>$121 (1150dh) partially refunded</td>
<td></td>
</tr>
<tr>
<td>CNOPS beneficiaries</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(public sector)</td>
<td>$6.3/60Dh of $31.5/300Dh, (20% patient contribution)</td>
<td>$24/230dh paid out of pocket of $121/1150 Dh</td>
<td>$24/230dh paid out of pocket of $121/1150 Dh</td>
<td>$25/240dh paid out of pocket of $126/1200 Dh</td>
<td>$24/230dh paid out of pocket of $121/1150 Dh</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$31.5/300Dh with 60-80% refund: $19-25/180-240Dh</td>
<td>$121/1150Dh with 60-80% refund: $72-97/690-920Dh</td>
<td>$121/1150Dh with 60-80% refund: $72-97/690-920Dh</td>
<td>$126/1200Dh with 60-80% refund: $76-101/720-960Dh</td>
<td>$121/1150Dh with 60-80% refund: $72-97/690-920Dh</td>
<td></td>
</tr>
</tbody>
</table>

- Out of pocket payment of $400/3800Dh without genotyping.

Out of pocket payment of $520/4950Dh with genotyping.

Refund rates of 80, 97 and 100% apply, but no refund for transport and ancillary exams.
<table>
<thead>
<tr>
<th>Persons with no health coverage</th>
<th>$31,5/300Dh</th>
<th>$121/1150Dh</th>
<th>$121/1150Dh</th>
<th>$126/1200Dh</th>
<th>$121/1150Dh</th>
<th>$400/3800Dh without genotyping.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$520/4950Dh with genotyping.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>excludes transport, ancillary exams.</td>
</tr>
</tbody>
</table>

*Table Cost, coverage and support for tests for people living with HCV in Morocco, Nov 2017*

Still at year’s end 2016, 34% of Moroccans were covered by AMO and its two funds CNSS & CNOPS. Despite refund rates of 80% minimum for some, the full cost must first be borne by the person, which may prove to be a significant barrier to care access. Patients must cover the full costs upfront before being refunded, which at $400 for viral load testing and FibroTest® or FibroScan® ($520 with genotyping), are on par with monthly average salary in Morocco ($500), and do not include transport, ancillary exams, and gastroenterological consultations costs.

At year’s end 2016, still, an estimated 35% of people had no health insurance, who, it is reasonable to assume, do not enjoy steady income. It is conceivable that costs of $400 to $520 for the tests only, discounting other costs, might be a real deterrent, especially for a disease that remains asymptomatic for many years.

*It is conceivable that costs of $400 to $520 for the tests only, discounting other costs, might be a real deterrent, especially for a disease that remains asymptomatic for many years.*

Patients must cover the full costs upfront before being refunded, which at $400 for viral load testing and FibroTest® or FibroScan® are on par with monthly average salary in Morocco ($500).

Private laboratories are authorized to perform all of these tests, and are of easier access to treatment seekers as such services may be closer to them and provide results faster than their public counterparts, with some results available the same day. However private testing is more expensive than public sector testing. If some upfront costs are partially refunded to AMO beneficiaries, those with no health coverage must bear the full cost.
The Ministry of Health (MoH) has clearly expressed its intent to develop and extend free coverage to more people, including students and independents. These measures will be crucial to developing the best possible response to HCV in Morocco, especially the MoH’s stated commitment to HCV elimination by 2030, which can only be achieved through effective free access to treatment.

**Issues around the prices paid by the Moroccan state for HCV diagnostics and monitoring tools**

*Graphic: Cumulative breakdown of care expenditure on HCV tests vs. treatment*
Despite significant drops in prices for sofosbuvir and daclatasvir, thanks to the absence of granted patent in Morocco and local production, a significant portion of the budget is allocated to pre and post treatment tests.

The chart above clearly indicates cost of treatment as the main challenge to people living with HCV, health professionals, and the MoH response to HCV. Despite significant drops in prices for sofosbuvir and daclatasvir, the two main DAAs, thanks to the absence of granted patent in Morocco and local production, a significant portion of the budget is allocated to treatment (74.5%), with the remainder allocated to pre and post treatment tests (25.5%). The issue of prices paid by the state, then, is crucial to public health response and to coverage for those living with HCV.

ANALYSIS OF PRICES PAID BY THE MOROCCAN STATE

Procurement process in Morocco

In Morocco, until recently, the National Institute of Hygiene (INH) was responsible for the procurement of medicine, reagents, and other health products. But now the DELM (Direction de l’Epidemiologie et de Lutte Contre les Maladies) is responsible for procurement, issuing calls for tenders, placing orders and planning inventory.

As part of the HIV component of the program financed by the Global Fund against AIDS, Tuberculosis and Malaria (GFATM), the purchase of antiretroviral drugs, diagnostics and reagent platforms occurs through GFATM’s Pooled Procurement Mechanism supply mechanism, the PPM, and particularly through the IDA foundation. Pooling volumes allow countries to negotiate lower prices for antiretroviral drugs and other health products than conventional contract signed directly with producers.

Pooling volumes allow countries to negotiate lower prices for antiretroviral drugs and other health products than conventional contract signed directly with producers.

The PPM is to be discontinued to make way for Wambo, a new pooled procurement platform, access to which might be available for countries outside GFATM grants as part of a commitment to countries non eligible for funding or countries whose eligibility is reduced as it succeeds in building local capacity and coverage.

Some countries such as India, Nepal, Ukraine, Georgia and Macedonia have managed to include the procurement of HCV treatment for people co-infected with HIV in the GFATM response. Otherwise, the GFATM’s response to viral hepatitis remains to this point very limited.
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Except in exceptional circumstances, and despite GFATM authorization for use their supported platforms to purchase medicines for viral hepatitis and other diseases, countries have not taken advantage of those procurement strategies used by GFATM HIV programs with regard to treatment or products and platforms needed for HCV diagnosis.

For lack of other options, Morocco had to issue ‘classic’ tenders to acquire required equipment: rapid tests, diagnostic platforms to perform HCV viral load, and the reagents required for each test.

Reagents registration procedure in Morocco

In Morocco, Article 2 of Law No. 17-04 on in vitro diagnostic reagents regulates registration terms and the use of reagents; ‘All and any reagents to be sold, free of charge or not, must be subject to registration with the administration. [...] A technical evaluation of performance is required for the provision of reagents.’ Other criteria may allow local health authorities to rule on the non-toxicity and efficacy of products: EU non-toxicity certification, FDA approval and the WHO prequalification.

<table>
<thead>
<tr>
<th>Reagents Safety Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Union</td>
</tr>
<tr>
<td>United States</td>
</tr>
<tr>
<td>World Health organization (WHO)</td>
</tr>
<tr>
<td>Morocco</td>
</tr>
</tbody>
</table>

Table Registration and regulation of diagnostic tests
ISSUES AROUND THE PRICES PAID BY THE MOROCCAN STATE FOR HCV DIAGNOSTICS AND MONITORING TOOLS

Above pictures: Example of diagnostic reagents and machines used in health institutions in Morocco
Sources/photos: Cepheid®, Abbott®, Fibroscan®, Roche®

The table below presents the equipments used in Morocco for diagnosis and monitoring tools for HCV.

<table>
<thead>
<tr>
<th>Where?</th>
<th>Equipment</th>
<th>Note</th>
<th>Time to results</th>
<th>Price per machine</th>
<th>Unitary price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>IPM, INH</td>
<td>Roche HCV VL &amp; Cobas® HCV GT</td>
<td>Screening &amp; quantification</td>
<td>192 tests over 8 hours</td>
<td>$150k (public price)</td>
</tr>
<tr>
<td>Pre-treatment Viral Load (VL) test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotyping (GT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where?</td>
<td>Equipment</td>
<td>Note</td>
<td>Time to results</td>
<td>Price per machine</td>
<td>Unitary price</td>
</tr>
<tr>
<td>--------</td>
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<td>------</td>
<td>----------------</td>
<td>------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>INH</td>
<td>Abbott M2000 5p</td>
<td></td>
<td></td>
<td>$170k (public price)</td>
<td>$10.50 VL and $22.50 VL, GT cost unknown</td>
</tr>
<tr>
<td>IPM (soon)</td>
<td>Abbott (model unknown)</td>
<td></td>
<td></td>
<td>$170k (public price)</td>
<td>$10.50 VL and $22.50 VL, GT cost unknown</td>
</tr>
<tr>
<td>IPM (soon)</td>
<td>Cepheid VL, HIV, VL HCV, Xpert HCV VL (FDA approved)</td>
<td>Pre &amp; post treatment VL</td>
<td>105 mins but different modules available</td>
<td>$11k to $17k (public price), $71,500 for 16 modules</td>
<td>$16.80 - $17.95</td>
</tr>
<tr>
<td>IPM</td>
<td>Inno-Lipa</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>IPM</td>
<td>Innogenetics (Abbott)</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
<td>as part of Global Fund’s HIV program</td>
<td>14 CEPHEID HIV VL, Xpert-HCV-VL (FDA approved)</td>
<td>Pre &amp; post treatment VL</td>
<td>105 mins but different modules available</td>
<td>$11k to $17k (public price), $71,500 for 16 modules</td>
</tr>
<tr>
<td>Liver fibrosis assessment</td>
<td>CHU Oujda, CHU Casablanca, CHU Rabat</td>
<td>FibroScan®</td>
<td>About $300,000 and $70,000 (minimum)</td>
<td>No reagents required but maintenance every six months</td>
<td></td>
</tr>
<tr>
<td>IPM</td>
<td>Actitest®/ Fibrotest®/ FibroMax®</td>
<td>Cost include access to Bioprédicte®’s proprietary software which is required to interpret test results</td>
<td></td>
<td>$59 FibroTest® $88 FibroMax®</td>
<td></td>
</tr>
</tbody>
</table>

Table: Platforms used in Morocco for HCV diagnosis and monitoring. Information on capacity and prices of the reagents are from MSF report source.¹⁶

Abbott, Roche and Cepheid benefit from a near-monopoly situation in terms of platforms used. Bulk and very large volume purchases are sometimes rewarded with lower unit costs but price variations are not very significant among these producers.

**ROCHE**
As part of the GFATM HIV program, Roche offers viral load test at a price of $9.40 (excluding maintenance of $20,000 per year and the $150,000 platform price) or $11.94 (including rental equipment and maintenance if the country agrees to perform at least 25,000 HIV viral loads per year). Yet, despite Morocco being in the list of countries eligible for this program, at year’s end 2017, Morocco continued to pay around $20 per Roche viral load test. Roche is the world leader in diagnostics for infectious diseases with nearly 30% market share (2008).

**ABBOTT**
For Abbott, prices drop when the country agrees to fixed length purchase commitments. From $25 per HIV/AIDS viral load test, prices drop to $13 if the country commits to three years. The price of the platform is itself of $170,000, excluding $18,000 maintenance per year.

**CEPHEID**
Morocco is also part of the Cepheid's special prices program. Prices quoted by Cepheid for HIV viral load ranged from $16.80 per test below 500,000 tests carried out to $14.75 to beyond 1.5 million tests.

**BIOCENTRIC**
Morocco does not have ‘open’ platforms, such as those of Biocentric for example, which have the advantage of being modular and open to the reactants and components of different brands. Biocentric bills $15 per unit. The price of the platform itself varies depending on the desired number of modules.
<table>
<thead>
<tr>
<th></th>
<th>Roche</th>
<th>Abbott</th>
<th>Cepheid</th>
<th>Biocentric (not available in Morocco)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV VL regular price</td>
<td>$9.4 (as per Roche HIV program), price paid: $20</td>
<td>$25</td>
<td>$16.8</td>
<td>$15, of which 7 for extraction reagents &amp; 8 for amplification reagents</td>
</tr>
<tr>
<td>Platform purchase and maintenance costs</td>
<td>$150k and $20k maintenance</td>
<td>$170k and $18k maintenance</td>
<td>$11k to $17,000 $71,500 for 16 modules</td>
<td>Total price with 4 extractors: $76480</td>
</tr>
<tr>
<td>Open platform</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>yes</td>
</tr>
</tbody>
</table>

Prices here are approximate and aim to present the lowest prices offered by these firms, in particular those offered as part of the GFATM’s PPM for HIV/AIDS.

The price of the reagents used to confirm the chronicity of HCV complicates and weighs heavily on the price of screening.

The purchase of equipment from manufacturers such Roche, Abbott and Cepheid forced buyers to also purchase reagents orders from the same manufacturer. In other words, the Moroccan public sector is equipped exclusively with closed platforms.

Biocentric offers platforms open to third party components and reagents.

The prices invoiced by Abbott, Roche and Cepheid, all close to each other, illustrate the quasi monopoly which these three manufacturers currently have in the Moroccan market.

If Biocentric, which has a CE certification, does not actually offer prices lower unit for each viral load test, Biocentric offers platforms open to third party components and reagents. An extractor cost $11,766 and a real-time thermocycler $29,416. If the platform has 4 extractors, between 200 and 300 tests per day can be carried out. The Biocentric platforms are the result of a partnership with the ANRS who required that the prices were the lowest possible.

While Roche seems to have its own raw material and production unit for reagents, Biocentric imports them from producer Thermo Fisher Scientific, one of the leading producers of raw materials reagents in the world. According to Biocentric, the price of the raw material for reagents increases every year.
As shown in the table above, platform prices vary significantly. Buying a single laboratory Roche platform (about $170,000 not including reagents or maintenance) costs as much as providing DAAs to 1,400 people with HCV (as per MSF’s pricing agreement). This illustrates the challenge countries with limited resources face in acquiring sufficient equipment to realize effective decentralization.

In parallel with a price renegotiation strategy for viral load tests, the country must also

**Patent Landscape**

It is also appropriate to map existing patents on HCV viral load testing technologies. Different types of patent may be in place, which may apply to products (instruments, reagents) or processes (extraction and amplification). For HIV viral loads, most of the patents on these products or processes, which had been filed by Abbott, Roche, Qiagen, Siemens, bioMérieux, Life Technologies, among others, have expired.

As in the case for medicine, producers of reagents and open platforms components are confronted with the same problems: disadvantageous licensing agreements with rights holder, price fluctuations, monopolies on raw material for reagents, and geographical limits of use of licensed products.

As for the viral load, the expiration of most the patents on these technologies, confirms that the less relevant strategy for local producers might be the resort to technology transfers, as those tie originator and patent holder producers to the other producers willing to produce these technologies, thus expending their monopoly beyond the patent term. By itself, the expiration of patents should allow any producer willing to do so to develop the technologies, either thanks to the disclosed information in the patent application, or by reverse engineering.

**Non-invasive liver fibrosis assessment technologies**

APRI or FIB-4 tests assess the progress of fibrosis by calculating a score, but are less accurate than FibroScan® and FibroTest®, particularly in cases of cirrhosis, which limits their use as part of the liver fibrosis assessment that is crucial to determining treatment strategy, including length of treatment, for people living with advanced cirrhosis.

Regarding other instruments of non-invasive liver fibrosis assessment, FibroScan® marketed by EchoSens, operates without reagent, which is a major asset, but the unit requires maintenance several times a year. A 'mini FibroScan®' is available for field use.

**The FibroTest®/ActiTest® technology outsources the interpretation of results through remote software.**

consider the optimal pooling of resources between HIV and viral hepatitis platforms. The samples collection system should also be reviewed to ensure optimal testing conditions for patients.

**This technology outsources the interpretation of results through remote software.**

The FibroTest®/ActiTest® are performed on a blood sample, which is a major advantage because the tests can be performed on the basis of samples which can be shipped. However, it is important to note that this technology outsources the interpretation of results through remote software which cannot
be purchased or used directly by the laboratory actually conducting the test, which must pay the software owner for each new result interpretation requested. This is the main drawback of this technology as the manufacturer has the ability to set prices unilaterally. Biopredictive laboratory, which markets the test, invoices each result between $59 and $88 regardless of the country.

The laboratory must pay the software owner Biopredictive between $59 and $88 for each new result interpretation requested.

<table>
<thead>
<tr>
<th></th>
<th>FibroScan® (EchoSens)</th>
<th>FibroTest® (Biopredictive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price per test</td>
<td>-</td>
<td>$59 - $88 (per test)</td>
</tr>
<tr>
<td>Platform Price</td>
<td>$300,000</td>
<td>$70,000 (mini)</td>
</tr>
</tbody>
</table>

FibroScan® and FibroTest® technologies are significant commercial success, at prices which are major barriers to access.

FibroScan® and FibroTest® are technologies derived from French public research.18

FibroScan® was developed by researchers who received public funding, first as part of INSERM and ESPCI.

FibroScan® was developed by researchers who received public funding, first as part of INSERM and ESPCI (Ecole Supérieure de Physique et de Chimie Industrielles). The research that led to FibroScan® was initially held at INSERM, in Mickael Tanter’s U979 laboratory. Dr. Laurent Sandrin, as part of his PhD on instinctual elastography at ESPCI Paris Tech, continued this research, which in particular lead to the development of the transient Vibration-Controlled Transient Elastography (VCTE).

‘Following this work, EchoSens was founded in June 2001 in order to transform this laboratory technique into a product. After 9 months of intensive development, the first prototype was developed: FibroScan® technology was born’.18 EchoSens, which patented FibroScan®, enjoyed in 2016 a turnover of 47.47 million.

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17 INSERM: ‘An ultra powerful elastography device measuring tissue elasticity, proven in the diagnosis of liver diseases and characterization of tumors. A new study confirms that this noninvasive approach outcome of the work of researchers at the Langevin Institute (Paris, Inserm Unit 979), performed as well as liver biopsy for the diagnosis of fibrosis.’
https://www.inserm.fr/actualites-et-evenements/actualites/imagerie-medicale-promesses-elastographie

18 EchoSens pioneer in quantitative elastography
http://www.echosenscorporate.com/fr/recherche-developpement
The FibroTest® was developed by the hepatology team at Pitié-Salpêtrière of AP-HP (Assistance Publique-Hôpitaux de Paris). AP-HP, alongside BioPredictive and INSERM, completed the development of the invention and patented it.

The FibroTest® was developed by the hepatology team at Pitié-Salpêtrière of AP-HP (Assistance Publique-Hôpitaux de Paris). AP-HP, alongside BioPredictive and INSERM, completed the development of the invention and patented it. An exclusive license has been granted to BioPredictive for commercialization. BioPredictive entrusted LabCorp, a US firm specializing in diagnostics, with the dissemination in the United States of its tests. In 2013, LabCorp sales stood at $5.8 billion.
The current model reproduces the same pattern. Initial research is funded by the public sector, then, either the public agency decides to patent and grant a license to a private firm (AP-HP/INSERM and BioPredictive model) or inventors develop discovery within a private structure (INSERM/ESPCI and EchoSens model).

In 2006, civil society organization Act Up-Paris was already very critical of such practices: 'Once on the market, these tools will be the cash cow of private startups which these visionaries attribute to their exclusive marketing yet were developed with public research funding and of which they are the main private shareholders. Then these generous 'specialists', people of little faith will quickly sell their exclusive operating license to the first pharmaceutical laboratory who’s generous enough.' 19

«Once on the market, these tools will be the cash cow of private startups which these visionaries attribute to their exclusive marketing yet were developed with public research funding and of which they are the main private shareholders».

The report of the UN’s High-Level Panel on Access to Medicines 20 calls for the use of open licenses in this type of situation. It also challenges common preconceptions surrounding the use of patents as a way for public institutions to finance themselves through royalties.

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19 Les marqueurs de fibrose (Protocole 45, Act Up-Paris, Dec 2006
http://www.actupparis.org/spip.php?article2838

20 p31, The United Nations Secretary-General’s High-Level Panel On Access To Medicines Report
https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/5596ed6d914e6b24d165ece26/150050753999/50923+-HLP+Report+-+ENGLISH+-+.web_v3.pdf
Non-exhaustive patent landscape in regards to non-invasive liver fibrosis assessment methods

As highlighted by this non exhaustive patent landscape made for the purpose of this report, pertaining to non-invasive methods for fibrosis assessment, research in this field is carried out largely in France in the context of public research.

<table>
<thead>
<tr>
<th>Patent/patent number</th>
<th>Priority date</th>
<th>Object</th>
<th>Applicant</th>
</tr>
</thead>
</table>
| WO/2015/150495       | 01/04/2014 (EP) | Methods For Assessing Whether A Patient Suffering From Chronic Hepatitis B Infection Is Associated With Moderate Or Advanced Fibrosis | - INSERM  
- Université Paris Diderot, Paris 7  
- Assistance publique Hôpitaux de Paris (AP-HP) |
| WO/2013/045843       | 27/09/2011 (FR)  | Method For Obtaining A Value Of A Score For Diagnosing The Stage Of Evolution Of Human Hepatic Fibrosis | - Centre hospitalier universitaire de Bordeaux  
- INSERM  
- AP-HP |
- Synchrotron Soleil  
- Université Paris Sud (Paris 11) |
- AP-HP |
| US20150374338        | 19/02/2013      | Multipulse Elastography Method                                         | Echosens |
| US20050251042        | 06/09/2002      | Device And Method For Measuring Elasticity Of A Human Or Animal Organ And For Two-Or Three-Dimensional Representation Thereof | Echosens |
| WO/2015/014763       | 02/08/2013      | Non-Invasive System For Calculating A Human Or Animal, Reliable, Standardized And Complete Score | Echosens |

It is interesting to note the presence of INSERM, an agency of which, ANRS, participates in the OPP-ERA program for open HIV viral load test platforms. Contacted, INSERM Transfert has not responded to our requests regarding potential interest in granting open licenses.
PART 3

COMPARATIVE STUDY BETWEEN MOROCCO AND OTHER COUNTRIES ON THE ISSUE OF HCV DIAGNOSTIC TESTS PRICES AND HCV MONITORING
Prices quoted here were collected in 2017 from October to November and may be subject to change.

The following have provided precious help in gathering data: Aair Azambuja (Brazil), Fatimata Ball (Mauritania), Souhaila Bensaid (Tunisia), Fouad Boutemak (Tunisia), Sylvie Boyer (Cameroon), Fanny Chabrol (Cameroon), Mohamed Chakroun (Tunisia), Lorena Di Giano (Argentina), Graciela Diap (Malaysia), Do Dang Dong (Vietnam), Mohammad El Nasser (Jordan), Manal El-Sayed (Egypt), Yasser Fayed (Egypt), Eric Fleutelot (Southeast Asia), Marcela Fogaça Vieira (Brazil), Saeed Hamid (Pakistan), Abdullah Hanatleh (Jordan), Giten Khwairakpam (India, Indonesia), Natalija Kravchenko (Ukraine), Myriam Lahlou-Filali (Morocco), Edward Low (Malaysia), Abigail Lukhwaro (Kenya), Liudmyla Maistat (Ukraine), Gwenaelle Maradan (Cameroon), Othman Mellouk (Egypt), Leena Menghaney (India), Edo Nasution (Indonesia), Fatiha Razik (Algeria), Yasmina Sebhi (Algeria), Olivier Segeral (Cambodia), Jirasak Sriparmong (Thailand), Caroline Thomas (Indonesia), Hafiz Azizur Rehman (Pakistan), Rita Wahab (Lebanon), Heba Wanas (Egypt), Serge Yota (Cameroon).

To provide better visibility prices have all been translated into US dollars (USD hereafter $), based on the exchange rate in force between the last week of October 2017 and the first week of November 2017, from the website www.xe.com, for the following currencies: Moroccan Dirham, Euro, Egyptian Pound, Tunisian Dinar, Algerian Dinar, Brazilian Real, Indian Rupee, Pakistani Rupee, Indonesian Rupiah, and Franc CFA. Other prices obtained were converted directly in US dollars and rounded where appropriate.

21 Currency conversion tool used by the report's author. http://www.xe.com/ft/
The geographical scope of this comparative study includes nineteen other countries which are Algeria, Argentina, Brazil, Cambodia, Cameroon, Egypt, Georgia, India, Indonesia, Jordan, Kenya, Kyrgyzstan, Lebanon, Malaysia, Pakistan, Thailand, Tunisia, Ukraine, and Vietnam.

<table>
<thead>
<tr>
<th>Country</th>
<th>World Bank lending status**</th>
<th>GDP/c* (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Argentina</td>
<td>Upper middle income country (UMIC)</td>
<td>13428</td>
</tr>
<tr>
<td>2  Lebanon</td>
<td>Upper middle income country (UMIC)</td>
<td>11945</td>
</tr>
<tr>
<td>3  Malaysia</td>
<td>Upper middle income country (UMIC)</td>
<td>10073</td>
</tr>
<tr>
<td>4  Brazil</td>
<td>Upper middle income country (UMIC)</td>
<td>8802</td>
</tr>
<tr>
<td>5  Jordan</td>
<td>Lower middle income country (LMIC)</td>
<td>5600</td>
</tr>
<tr>
<td>6  Thailand</td>
<td>Upper middle income country (UMIC)</td>
<td>5426</td>
</tr>
<tr>
<td>7  Algeria</td>
<td>Upper middle income country (UMIC)</td>
<td>4345</td>
</tr>
<tr>
<td>8  Tunisia</td>
<td>Lower middle income country (LMIC)</td>
<td>3985</td>
</tr>
<tr>
<td>9  Georgia</td>
<td>Lower middle income country (LMIC)</td>
<td>3720</td>
</tr>
<tr>
<td>10 Indonesia</td>
<td>Lower middle income country (LMIC)</td>
<td>3416</td>
</tr>
<tr>
<td>11 Egypt</td>
<td>Lower middle income country (LMIC)</td>
<td>3304</td>
</tr>
<tr>
<td>12 Morocco</td>
<td>Lower middle income country (LMIC)</td>
<td>3077</td>
</tr>
<tr>
<td>13 Vietnam</td>
<td>Lower middle income country (LMIC)</td>
<td>2171</td>
</tr>
<tr>
<td>14 Ukraine</td>
<td>Lower middle income country (LMIC)</td>
<td>2109</td>
</tr>
<tr>
<td>15 India</td>
<td>Lower middle income country (LMIC)</td>
<td>1688</td>
</tr>
<tr>
<td>16 Kenya</td>
<td>Lower middle income country (LMIC)</td>
<td>1432</td>
</tr>
<tr>
<td>17 Pakistan</td>
<td>Lower middle income country (LMIC)</td>
<td>1427</td>
</tr>
<tr>
<td>18 Cameroon</td>
<td>Lower middle income country (LMIC)</td>
<td>1234</td>
</tr>
<tr>
<td>19 Kyrgyzstan</td>
<td>Lower middle income country (LMIC)</td>
<td>1198</td>
</tr>
<tr>
<td>20 Cambodia</td>
<td>Lower middle income country (LMIC)</td>
<td>1140</td>
</tr>
</tbody>
</table>

*Table: Scope countries ranked by World Bank classifications (income level) and IMF 2015 per capita GDP (wages per person per year).


*Countries World Bank ranking: UMIC = Upper middle Income Country / LMIC = Lower Middle Income Country.
All are classified as Middle Income Countries by the World Bank (WB) socio-economic ranking. WB classification further distinguishes between Upper and Lower Middle Income Countries (UMIC & LMIC respectively), and the International Monetary Fund (IMF) also provides per capita Gross Domestic Product (GDP) figures in USD for all countries in the scope in its 2015 ranking, akin to an approximate average yearly wage.

HCV POPULATION AND PREVALENCE IN SCOPE COUNTRIES

Scope countries include one country of more than a billion people (India) and countries such as Jordan, Lebanon, Kyrgyzstan and Georgia with no more than ten million people.

<table>
<thead>
<tr>
<th>Country</th>
<th>Population (2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>1,290,750,681</td>
</tr>
<tr>
<td>Indonesia</td>
<td>265,252,084</td>
</tr>
<tr>
<td>Pakistan</td>
<td>207,774,520</td>
</tr>
<tr>
<td>Brazil</td>
<td>206,081,432</td>
</tr>
<tr>
<td>Egypt</td>
<td>94,798,827</td>
</tr>
<tr>
<td>Vietnam</td>
<td>92,699,227</td>
</tr>
<tr>
<td>Thailand</td>
<td>68,229,099</td>
</tr>
<tr>
<td>Ukraine</td>
<td>45,426,200</td>
</tr>
<tr>
<td>Argentina</td>
<td>43,431,886</td>
</tr>
<tr>
<td>Kenya</td>
<td>41,800,000</td>
</tr>
<tr>
<td>Algeria</td>
<td>41,300,000</td>
</tr>
<tr>
<td>Morocco</td>
<td>33,848,242</td>
</tr>
<tr>
<td>Malaysia</td>
<td>30,417,000</td>
</tr>
<tr>
<td>Cameroon</td>
<td>24,229,247</td>
</tr>
<tr>
<td>Cambodia</td>
<td>15,708,756</td>
</tr>
<tr>
<td>Tunisia</td>
<td>10,982,754</td>
</tr>
<tr>
<td>Jordan</td>
<td>9,531,712</td>
</tr>
<tr>
<td>Lebanon</td>
<td>6,237,738</td>
</tr>
<tr>
<td>Kyrgyzstan</td>
<td>5,727,553</td>
</tr>
<tr>
<td>Georgia</td>
<td>3,729,500</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>HCV prevalence (in %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egypt</td>
<td>10</td>
</tr>
<tr>
<td>Georgia</td>
<td>7,7</td>
</tr>
<tr>
<td>Pakistan</td>
<td>6,8</td>
</tr>
<tr>
<td>Cameroon</td>
<td>4,9</td>
</tr>
<tr>
<td>Ukraine</td>
<td>3,6</td>
</tr>
<tr>
<td>Malaysia</td>
<td>2,5</td>
</tr>
<tr>
<td>Kyrgyzstan</td>
<td>2,5</td>
</tr>
<tr>
<td>Cambodia</td>
<td>2,3</td>
</tr>
<tr>
<td>Vietnam</td>
<td>2,2</td>
</tr>
<tr>
<td>Jordan</td>
<td>2,1</td>
</tr>
<tr>
<td>Thailand</td>
<td>2,0</td>
</tr>
<tr>
<td>Algeria</td>
<td>2,0</td>
</tr>
<tr>
<td>Tunisia</td>
<td>1,8</td>
</tr>
<tr>
<td>Argentina</td>
<td>1,5</td>
</tr>
<tr>
<td>Brazil</td>
<td>1,3</td>
</tr>
<tr>
<td>Morocco</td>
<td>1,2</td>
</tr>
<tr>
<td>Kenya</td>
<td>0,9</td>
</tr>
<tr>
<td>India</td>
<td>0,8</td>
</tr>
<tr>
<td>Indonesia</td>
<td>0,8</td>
</tr>
<tr>
<td>Lebanon</td>
<td>0,2</td>
</tr>
</tbody>
</table>

"Scope countries ranked by population size. Source: www.mapcrowd.org"
Morocco is ranked twelfth in population, in line with its per capita GDP ranking in the IMF ranking. HCV prevalence is highest in Egypt, with 10% of the general population living with HCV, followed by Georgia, Pakistan, and Cameroon. Morocco, at 1.2% enjoys low prevalence, relative to most scope countries, comforting the Ministry of Health’s ambition of full HCV elimination by 2030.

**TABLE HCV DIAGNOSTICS AND MONITORING PRICES, RATES AND ACCESS IN SCOPE COUNTRIES**

Disclaimer: prices quoted in the table below are informational, for comparison purposes only, and were collected 2017 October to November.

<table>
<thead>
<tr>
<th>Country</th>
<th>Sector/market</th>
<th>Rapid tests</th>
<th>Serology</th>
<th>Viral load</th>
<th>Genotyping</th>
<th>Fibrotest®/FibroScan®</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Algeria</td>
<td>Ministry of health (MoH) purchase price</td>
<td>$7, not yet widely available</td>
<td>-</td>
<td>$44.2 (Abbott RealTime)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td></td>
<td></td>
<td>$173</td>
<td>$173 as part of WHO program</td>
<td>$129.7-$209 ActiTest®/FibroTest®</td>
</tr>
<tr>
<td></td>
<td>Public : centralized purchase (CP)</td>
<td>$2.38 (Price of reagents)</td>
<td>-</td>
<td>$82.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Argentina</td>
<td>Public : MoH's CP</td>
<td>$0,5 (ALERE S/A)</td>
<td>-</td>
<td>$18 (Abbott)</td>
<td>$57.2 (Abbott)</td>
<td>$278,142 Price of FibroScan® equipment</td>
</tr>
<tr>
<td></td>
<td>Accessible to all</td>
<td>Free through Sistema Único de Saúde, but some delays in results’ return dependant on availability and geographic location: an average of 4 months to complete all tests and then 3 months before starting treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Sector/market</td>
<td>Rapid tests</td>
<td>Serology</td>
<td>Viral load</td>
<td>Genotyping</td>
<td>Fibrotest®/FibroScan®</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------</td>
<td>-------------</td>
<td>----------</td>
<td>------------</td>
<td>------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Brazil</td>
<td>Private: Fleury, São Paulo</td>
<td>-</td>
<td>$77.6 - $317</td>
<td>$290</td>
<td>$337</td>
<td>$125.1 (FibroScan®)</td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td>$1 (SD Bioline)</td>
<td>$10 (ELISA)</td>
<td>$18 Xpert, $30 Omnis – Biocentric, $95 Roche, Institut Pasteur Cambodia</td>
<td>$75 (Roche)</td>
<td>$50 FibroScan®, little used. FibroTest®</td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>-</td>
<td>-</td>
<td>$60 (Abbott)</td>
<td>-</td>
<td>$50 (FibroScan®)</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Public (Hôpital Central de Yaoundé)</td>
<td>-</td>
<td>$14 (approx)</td>
<td>$107</td>
<td>$152</td>
<td>$143.6</td>
</tr>
<tr>
<td></td>
<td>Institut Pasteur Cameroun</td>
<td>-</td>
<td>$15.9</td>
<td>$111.3</td>
<td>$146.6</td>
<td>$157 (FibroTest®)</td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>-</td>
<td>$11.5</td>
<td>$276</td>
<td>$336.4</td>
<td>$91.8 (Fibrotest)</td>
</tr>
<tr>
<td>Cameroon</td>
<td>Centralized purchasing</td>
<td>$0.3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td>$1.1</td>
<td>$1.1</td>
<td>$14</td>
<td>$5.7</td>
<td>$8.5 (FibroScan®)</td>
</tr>
<tr>
<td></td>
<td>Private sector two examples</td>
<td>$2.8</td>
<td>-</td>
<td>$28</td>
<td>$14</td>
<td>$28 (FibroScan®) $85- $102 (FibroTest®)</td>
</tr>
<tr>
<td></td>
<td>Pharco</td>
<td>$27.4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Pharco laboratory has an agreement with different laboratories and thus offers all of these tests as a single package</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Georgia</td>
<td>Public: MoH price</td>
<td>$199.5</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>of which most vulnerable recipients are refunded 70% and other recipients 30%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$60 final out of pocket for most vulnerable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$140 final pay out of pocket for the rest of the population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Sector/market</td>
<td>Rapid tests</td>
<td>Serology</td>
<td>Viral load</td>
<td>Genotyping</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>--------------------------------</td>
<td>------------------------------</td>
<td>--------------------------------------------------</td>
<td>---------------------</td>
<td>------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>8. India</td>
<td>Negotiated community programs</td>
<td>Free</td>
<td>Generically produced / provided by generic pharmaceutical companies</td>
<td>$36.9</td>
<td>Genotyping not available as stand alone</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$66.2</td>
<td>Viral load &amp; genotyping</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Public prices</td>
<td>$118.6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Indonesia</td>
<td>Negotiated community programs</td>
<td>$1 (Fokus Diagnostic)</td>
<td>-</td>
<td>$0 - $31</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prices as advertised</td>
<td>$13.6 - $29.5</td>
<td>$110.6 - $221.1</td>
<td>$272.7</td>
<td>$73.7 (FibroScan®)</td>
<td></td>
</tr>
<tr>
<td>10. Jordan</td>
<td>Public</td>
<td>-</td>
<td>$5</td>
<td>$75 only available in Amman, Irbid and Zarqa</td>
<td>$130 only available in Amman, Irbid and Zarqa</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td>$1.1</td>
<td>$1.1</td>
<td>$14</td>
<td>$5.7 (FibroScan®)</td>
<td></td>
</tr>
<tr>
<td>11. Kenya</td>
<td>Mainly private</td>
<td>$1</td>
<td>-</td>
<td>$70 - $150 posted to South Africa Laboratories. It takes about two weeks to get the results</td>
<td>$120 - $150 posted to South Africa Laboratories. It takes about two weeks to get the results</td>
<td></td>
</tr>
<tr>
<td>12. Kyrgyzstan</td>
<td>-</td>
<td>$6</td>
<td>-</td>
<td>$36</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Sector/market</td>
<td>Rapid tests</td>
<td>Serology</td>
<td>Viral load</td>
<td>Genotyping</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>---------------</td>
<td>-------------</td>
<td>-------------------</td>
<td>--------------------</td>
<td>-------------------</td>
<td></td>
</tr>
<tr>
<td>13. Lebanon</td>
<td>Public</td>
<td></td>
<td>$26</td>
<td>$200</td>
<td>$175</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Harm reduction center « Escale »</td>
<td>$0, Gilead donation</td>
<td>$0, Gilead donation</td>
<td>$0, Gilead donation</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>14. Malaysia</td>
<td>Public</td>
<td>$8</td>
<td>$58</td>
<td>$83</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>$35</td>
<td>$105</td>
<td>$116</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Morocco</td>
<td>Public</td>
<td>$1.2-$2.1</td>
<td>$31.5 -$36.8 reagents</td>
<td></td>
<td>$31.5 -$36.8 reagents</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Pakistan</td>
<td>Public</td>
<td>$0.5-$1.1</td>
<td>$3.8 paid, of $7</td>
<td>$18.9 paid by patient, of $80</td>
<td>$28.4 - $94.9 paid by patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>$3.3- $5.2</td>
<td>$4.7, $15, $17</td>
<td>$57-$150</td>
<td>$150</td>
<td></td>
</tr>
<tr>
<td>17. Thailand</td>
<td>Public</td>
<td>$3-8</td>
<td>$83-85</td>
<td>$117-120</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Tunisia</td>
<td>MoH price</td>
<td>$0.8-$2</td>
<td></td>
<td>$20.2-40.4</td>
<td>$24.2-48.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td></td>
<td>$10.8</td>
<td>$10.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td></td>
<td>$19</td>
<td>91</td>
<td>$73</td>
<td></td>
</tr>
</tbody>
</table>
The table above shows different rates and prices in the twenty scope countries. This table illustrates the complexity of the issue of prices and rates charged by public and private laboratories and highlights 'market segmentation', ie different prices in the same country based on active programs or within the various sectors.

The table illustrates the complexity of the issue of prices and rates charged by public and private and highlights 'market segmentation'.

In each column is a different consideration: Rapid tests, Serological tests (Serology), Viral load testing (pre and post treatment), Genotyping test and finally Liver fibrosis non-invasive evaluation tests. For each country, a different line will indicate whether costs are in the public or the private sector, a negotiated community program (as is the case in India and Indonesia) or paid by the Ministry of health.

Indeed, for the public sector, it is important to distinguish the price paid by state institutions and those paid by people.

It is also interesting to identify national responses where free access has, or has not, led to widespread use. It was unfortunately not possible within the scope of this study to provide systematically detailed information about health coverage deployed in each country, private insurances schemes, or the implementation of decentralization.

The objective of this study is to analyze the results in light of available information and identify trends in prices of HCV diagnostic tools in countries with a socio-economic status similar to that of Morocco.
RAPID TESTS AND SEROLOGICAL TESTS

Rapid tests are not yet available in all scope countries, but where these have been brought to market, prices average around $1. For countries such as Egypt, Brazil, Tunisia, the unit price through bulk purchasing is even below $0.5. This strategy could apply as well for countries such as Morocco, where their use is not yet widespread. Sometimes these tests are provided 'free' by pharmaceutical companies, such as Pharco in Egypt, Gilead in Lebanon under certain programs, or generic producers in India. Generic DAAs producers in Morocco do not currently practice this.

In Algeria, Beker offers the combination of Sofosbuvir/ Daclatasvir and all the diagnostic and monitoring assay as a package for $1247. This move has not been yet made par generic producers in Morocco.

As for the conventional serological tests, if prices are not as low as those of rapid tests, they rarely exceed $10 in the public sector.

VIRAL LOAD AND GENOTYPING

Viral load testing is essential to the diagnosis and monitoring of Hepatitis C Virus (HCV). The viral load is performed to confirm the chronicity of infection then allows the monitoring of the person during and after the treatment. The table above shows that the lowest prices for viral loads are those of Egypt ($14) and Brazil ($18). To enjoy such prices, Brazil's MoH bought 90,000 HCV reagents from Abbott. As for Egypt, it is the country most affected by HCV in terms of prevalence, with more than ten million people requiring treatment.

What are the factors behind such prices?

If the price of reagents is slightly responsive, bulk purchases do not have a significant impact on the price of reagents. One must also consider the large number of countries which appear to use Roche and Abbott equipment and reactives. Roche—with a 30% market share in diagnostics of infectious diseases in 2008—and Abbott seem to enjoy a monopoly. In Morocco, the prices paid by the National Agency for Health Insurance (ANAM) for viral load testing and genotyping are among the highest prices paid by the public sector in scope countries.

As for genotyping, this test is not yet widely available. The lowest prices are found in Egypt, Tunisia and Ukraine.
The graph above shows different reagents purchase price required for viral load testing as per centralized or pool purchases in four different countries. The price for Morocco is twice as high as that paid by Brazil and Egypt.

LIVER FIBROSIS EVALUATION TESTS

Non-invasive fibrosis assessment is based on FibroScan®, which requires no reagents or samples, but demands the patient to attend an equipped venue, and the machine can not perform two or more tests simultaneously. Its high unit price also contributes to complicate or limit its use.

As for the FibroTest®, which requires outsourcing of interpreting the results, it is not an attractive solution as the manufacturer is in a position of power and can almost unilaterally set prices.

Echosens and BioPredictive, which technologies are derived from the public research, are in a near-monopoly situation on these two technologies and impose their prices everywhere in the world.

TEST VENUES CLUSTERED IN CAPITAL CITIES

These tests are performed mostly in larger cities, mainly in the capital cities, sometimes in only two cities, is the case in Jordan and Algeria in particular.

Scope country analysis also shows that tests are performed mostly in larger cities, mainly in the capital cities, sometimes in only two cities, is the case in Jordan and Algeria in particular. In Kenya, the tests are not performed in-country but samples are shipped to South Africa. Where tests are outsourced in this way, deadlines are sub-optimal and prices are potentially higher, thereby creating serious bottlenecks for large-scale national HCV programs.
Health coverage systems vary significantly from one country to another, as well as within each country, as clearly illustrated by the example of Morocco. In Brazil, the health system is universal. Everyone has access to health care for free. In Vietnam, however, people must pay out of pocket, and then are reimbursed if they have private insurance. In Ukraine, some care is free prescribed. In Georgia, the poorest people are reimbursed up to 70% of care, against 30% for the rest of the population.

The case of Brazil

In Brazil, the public health system (Sistema Unico de Saúde) provides universal health coverage. In theory, all HCV testing is free for people under SUS. But its availability varies by geographic areas and waiting. On average, it takes 4 months to get all the results, then another three months wait to receive treatment. In other words, 7 months from first testing to treatment initiation.

That’s why many people, mostly middle class and up, are turning to private laboratories, which charge very high prices. For example, private laboratory ‘Fleury’ in Sao Paulo invoices $77.6 and $317 for a serological test, $290 for viral load testing, $337 for genotyping, and $125 for a FibroTest® test.

Under specific circumstances, people registered with private insurance will be refunded tests performed in the private sector.
The geographical scope of this comparative study includes six countries in the Middle East North Africa region and one EMRO country, Pakistan, as well as Morocco.

<table>
<thead>
<tr>
<th>Country</th>
<th>World Bank status*</th>
<th>Average salary per inhabitant**</th>
<th>HCV prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Lebanon</td>
<td>UMIC</td>
<td>$765.8</td>
<td>0.2%</td>
</tr>
<tr>
<td>2 Algeria</td>
<td>UMIC</td>
<td>$400</td>
<td>2%</td>
</tr>
<tr>
<td>3 Jordan</td>
<td>LMIC</td>
<td>$393.3</td>
<td>2.1%</td>
</tr>
<tr>
<td>4 Tunisia</td>
<td>LMIC</td>
<td>$345.8</td>
<td>1.8%</td>
</tr>
<tr>
<td>5 Egypt</td>
<td>LMIC</td>
<td>$250</td>
<td>10%</td>
</tr>
<tr>
<td>6 Morocco</td>
<td>LMIC</td>
<td>$245.8</td>
<td>1.2%</td>
</tr>
<tr>
<td>7 Pakistan</td>
<td>LMIC</td>
<td>$105</td>
<td>6.8%</td>
</tr>
</tbody>
</table>

* Countries ranking by the World Bank - UMIC = Upper middle Income Country / LMIC = Lower Middle Income Country  
** Average income according to the 2012 World Bank ranking except for Algeria, data available for 2007. Epidemiological data available from: www.mapcrowd.org

In epidemiological terms, Egypt and Pakistan are the two countries with the highest prevalence (10% and 6.8% respectively). The other 5 countries have prevalence rates of between 0.2 and 2.1%.

In terms of average gross wage per capita, Morocco is penultimate before Pakistan. Lebanon and Algeria are top. Egypt and Morocco are very close. Using average wages as a yardstick allows for more precise interpretation of actual health expenditure for which people pay out-of-pocket.

22 Regional Office for the Eastern Mediterranean (EMRO)
<table>
<thead>
<tr>
<th>Country</th>
<th>Sector/market</th>
<th>Rapid tests</th>
<th>Serological tests</th>
<th>Viral load</th>
<th>Genotyping</th>
<th>Fibrotest®/FibroScan®</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Algeria</td>
<td>Ministry of health (MoH) purchase price</td>
<td>$7, not yet widely available</td>
<td>-</td>
<td>$44.2 (Abbott RealTime)</td>
<td>Not available to the public</td>
<td>FibroScan®: Free in Hepatology And Infectious Diseases Units</td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td>-</td>
<td>Free but available only in Algiers and Constantine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>-</td>
<td>$8.6</td>
<td>$173</td>
<td>$173 as part of WHO program</td>
<td>ActiTest®/FibroTest® $129.7-$209</td>
</tr>
<tr>
<td>2. Egypt</td>
<td>Centralized purchasing</td>
<td>$0.3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td>$1.1</td>
<td>$1.1</td>
<td>$14</td>
<td>$5.7</td>
<td>$8.5 (FibroScan®)</td>
</tr>
<tr>
<td></td>
<td>In the public sector, civil servants are 100% covered by the national program.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Private sector two examples</td>
<td>$2.8</td>
<td>-</td>
<td>$28</td>
<td>$14</td>
<td>$28 (FibroScan®) $85-$102 (FibroTest®)</td>
</tr>
<tr>
<td></td>
<td>Pharco</td>
<td>$27.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pharco laboratory has an agreement with different laboratories and thus offers all of these tests as a single package</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Jordan</td>
<td>Public</td>
<td>-</td>
<td>$5</td>
<td>$75 only available in Amman Irbid and Zarqa</td>
<td>$130 only available in Amman Irbid and Zarqa</td>
<td>-</td>
</tr>
<tr>
<td>Country</td>
<td>Sector/market</td>
<td>Rapid tests</td>
<td>Serological tests</td>
<td>Viral load</td>
<td>Genotyping</td>
<td>Fibrotest®/FibroScan®</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------</td>
<td>-------------</td>
<td>-------------------</td>
<td>------------</td>
<td>------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>4. Lebanon</td>
<td>Public</td>
<td>$26</td>
<td>$200</td>
<td>$175</td>
<td></td>
<td>$152 (FibroScan®)</td>
</tr>
<tr>
<td></td>
<td>Harm reduction center ‘l’Escale’</td>
<td>$0, Gilead donation</td>
<td>$0, Gilead donation</td>
<td>-</td>
<td>$0, Gilead donation</td>
<td></td>
</tr>
<tr>
<td>5. Morocco</td>
<td>Public</td>
<td>$1.2-$2.1</td>
<td>$31.5 - $36.8 reagents</td>
<td>$31.5 - $36.8 reagents</td>
<td>$126 (AMO)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>-</td>
<td>$105-$126</td>
<td>$121 (AMO)</td>
<td>$126 (AMO)</td>
<td>$126</td>
</tr>
<tr>
<td>6. Pakistan</td>
<td>Public</td>
<td>$0.5-$1.1</td>
<td>$3.8 paid, of $7</td>
<td>$18.9 paid by patient, of $80</td>
<td>$28.4-$94.9 paid by patient</td>
<td>$18.9 - $20 (FibroScan®)</td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>$3.3-$5.2</td>
<td>$4.7, $15, $17</td>
<td>$57-$150</td>
<td>$150</td>
<td>$56.9, $80, $114 (FibroScan®)</td>
</tr>
<tr>
<td>7. Tunisia</td>
<td>MoH price</td>
<td>$0.8-$2</td>
<td>-</td>
<td>$20.2-$40.4</td>
<td>$24.2-$48.4</td>
<td>$40.4 (FibroScan®) $48.4 (FibroTest®)</td>
</tr>
<tr>
<td></td>
<td>Public</td>
<td>$10.8</td>
<td>$10.4</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Private</td>
<td>$19</td>
<td>91</td>
<td>$73</td>
<td>$91</td>
<td>(FibroScan®)</td>
</tr>
</tbody>
</table>

**ALGERIA**

In Algeria, rapid tests are not yet widely available. Those tests which are available in the country are free but are available in public sector establishments in only two cities, Algiers and Constantine. Genotyping is not available in the public sector but is sometimes practiced in other settings such as international programs. FibroScan® is free and performed at the department for infectious diseases and hepatology. In the private sector, the FibroTest® is much more expensive.
EGYPT

In Egypt, in the public sector, most patients attend the Liver Institute to benefit from the national treatment program. People pay the clinical laboratory between $0.5 and $0.6 to perform a rapid test. Then people can choose to either move to the private sector or, if they cannot pay, to the public sector. In the latter case the individual must make a formal request. A decision is usually made within a month. The tests include viral load and blood tests to measure liver enzymes. But the wait for tests results sometimes is rather extended.

Civil servants are supported by the public sector and all of their tests are covered by their health insurance system.

People who want to save time often move to the private sector, which charges higher rates but allows them to avoid long waits. Rates vary from one laboratory to another, and some people with private coverage may be reimbursed either in part or entirely.

Also note that in the context of a specific program, the Egyptian laboratory Pharco has an agreement with various laboratories and offers all the tests for a total of $27.4.

JORDAN

In Jordan, rapid tests are not available. In the public sector, the viral load and genotyping tests are only available in two cities, Irbid and Zarqa (Amman). FibroScan® and FibroTest® are not available.

LEBANON

Lebanon, with the lowest prevalence of this comparative study, is the country with the highest prices in the public sector ($200 for Viral Load, $175 for Genotyping and $152 for FibroScan®).

However, as part of a specific program called ‘Escale’, Gilead pays for ‘free’ rapid tests. In case of a positive result, Gilead also pays for Viral Load testing. In case of confirmation of chronic HCV, Gilead agrees to cover fees a FibroScan®. People then pay $20 to finalize their file with the MoH, who in turn provides access to Gilead’s treatment.
PAKISTAN

In the public sector, the viral load test is free in the south of Punjab province and $19 in central and northern Punjab. In the private sector, prices range from $38 and $114. Genotype testing is not available in the public sector of Punjab province and in the private sector it costs between $57 and $142. HCV diagnostics are available in the private market in Pakistan. Anyone can make an appointment a week in advance, and most government hospitals perform tests three days a week.

TUNISIA

Tunisia enjoys relatively low rates in the public sector of $0.8 for a rapid test, and between $20 and $40 for viral load, genotyping or FibroScan®. If these prices are still quite high, particularly the viral load and genotyping, they remain much lower than prices in Pakistan, Jordan, Lebanon’s public sector, or than the purchase price in Algeria ($44.2).

The chart opposite shows the different prices of a viral load test in the public sector in six countries of the MENA region; Egypt, Pakistan, Tunisia, Morocco and Lebanon. Morocco and Lebanon are the countries with the highest prices. One might think that overall prevalence in Egypt (10%) and Pakistan (6.8%) and associated purchase sizes would help lower these prices compared to other countries in the region. But the analysis of expenditure in Morocco and the different rates applied by providers of HCV viral load test (see previous section) shows that the price of $15 is possible (Biocentric). By comparison, the rates applied in other MENA countries appear abnormally high.

Chart: Price of Viral Load Test in the public sector in different countries MENA & EMRO countries (Egypt, Jordan, Lebanon, Morocco, Pakistan, Tunisia).
The chart opposite shows the different prices reported for the Fibroscan® test in five countries of the region. The chart does not include Jordan, as this test is not available in the public sector. As in the previous chart, prices in Morocco and Lebanon are much higher than in Egypt, Pakistan and Tunisia.

As in the previous charts, the prices in Morocco are particularly high, although lower than prices in Jordan and Lebanon.

**Prices in Morocco vs. lowest scope price**

MSF announced in October 2017 that they had negotiated an agreement for the provision of a 3-month sofosbuvir and daclatasvir combination treatment at $120 for 11 low income countries. According to the organization, the agreement will allow a large number of people to access to treatment.
Prices in early Nov 2017 in Morocco:

**SOFOSBUVIR** : 28 pills:

- PHARMAS: US$315 (3000dh)
- GALENICA: US$315 (3000dh)

**SOFOSBUVIR + LEDIPASVIR/28 pills**:
- MYLAN PHARMA. S.A.S: US$458 (4340dh)

**DACLATASVIR/28 pills**:
- PHARMAS: US$163 (1549dh)
- GALENICA: US$157 (1500dh)

HCV chronicity, fibrosis evaluation, and genotyping tests and monitoring of the person, public sector prices.

**Lowest price composed of**:

- SOFOSBUVIR + DACLATASVIR:
  - Price as per Doctors Without Borders’ (MSF) October 2017 agreement

HCV chronicity, fibrosis evaluation, and genotyping tests and monitoring of the person, as per Egypt public sector price as part of national program

---

**Graphic**: prices in Morocco vs. the cheapest price charged in other countries.
<table>
<thead>
<tr>
<th></th>
<th>Morocco</th>
<th>diagnostic prices treatment in Egypt (MSF countries program)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral load 1</td>
<td>$121</td>
<td>$14</td>
</tr>
<tr>
<td>Genotype</td>
<td>$121</td>
<td>$5.7</td>
</tr>
<tr>
<td>FibroTest ® or FibroScan®</td>
<td>$126</td>
<td>$8.5</td>
</tr>
<tr>
<td>Viral load 2</td>
<td>$121</td>
<td>$14</td>
</tr>
<tr>
<td>Daclatasvir (3 months)</td>
<td>$471</td>
<td>$120 (MSF program)</td>
</tr>
<tr>
<td>Sofosbuvir (3 months)</td>
<td>$945</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>$1905</td>
<td>$162.2</td>
</tr>
</tbody>
</table>

**Table: Prices charged in Morocco vs. the cheapest price charged in other countries.**

**Graphic: Public sector diagnostic cost versus the cheapest price in the scope.**
### Table: Public sector diagnostic cost in Morocco with and without genotyping versus cheapest scope price.

<table>
<thead>
<tr>
<th></th>
<th>Public sector</th>
<th>Morocco</th>
<th>Egypt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral load 1</td>
<td></td>
<td>$121</td>
<td>$14</td>
</tr>
<tr>
<td>Genotyping</td>
<td></td>
<td>$121</td>
<td>$5.7</td>
</tr>
<tr>
<td>FibroTest ® or FibroScan®</td>
<td></td>
<td>$126</td>
<td>$8.5</td>
</tr>
<tr>
<td>Viral load 2</td>
<td></td>
<td>$121</td>
<td>$14</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>$489</td>
<td>$42.2</td>
</tr>
</tbody>
</table>

### Without genotyping

<table>
<thead>
<tr>
<th></th>
<th>Public sector</th>
<th>Morocco</th>
<th>Egypt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral load 1</td>
<td></td>
<td>$121</td>
<td>$14</td>
</tr>
<tr>
<td>FibroTest ® or FibroScan®</td>
<td></td>
<td>$126</td>
<td>$8.5</td>
</tr>
<tr>
<td>Viral load 2</td>
<td></td>
<td>$121</td>
<td>$14</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>$368</td>
<td>$36.5</td>
</tr>
</tbody>
</table>

Graphs and charts above compare the total cost of all tests necessary to HCV monitoring in Morocco and Egypt, first with then without genotyping. Prices quoted here exclude other 'out-of-pocket' expenses such as fees for medical appointments and the upfront cost of DAA treatment (sofosbuvir-daclatasvir), which, even at lowest available Moroccan market price, is significantly higher than the price obtained by Egyptian health authorities or by MSF in their brokered procurement agreement of October 2017.

The graph below summarizes information mentioned in this comparative study. Percentages (%) in bold at the end of each line correspond to the ratio of total test costs to monthly GNI per capita in the country, in effect providing a measure of how many months of wages would have to be spent to cover diagnosis.

<table>
<thead>
<tr>
<th>Country</th>
<th>Public Sector</th>
<th>Private Sector</th>
<th>GNI per capita</th>
<th>Serological test or rapid test</th>
<th>Viral load</th>
<th>Genotyping</th>
<th>Fibroscan or Fibrotest</th>
<th>Not detailed</th>
<th>Ratio (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Egypt</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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**Table: Diagnostics & Treatment costs measured relative to average monthly wages**
Morocco and Lebanon topped the list of the highest public sector prices in the MENA region for viral load testing, genotyping and Fibroscan®. These prices do correlate with the purchase costs of reagents. In Morocco, it would cost more than twice the monthly per capita GNI to cover all the diagnostic tests required for HCV response. In Morocco, it would cost more than twice the monthly per capita GNI to cover all the diagnostic tests required for HCV response. By this yardstick, prices are the lowest in Egypt. Total cost are the highest in Lebanon and Algeria, while Pakistan and Morocco pay the most as expressed against monthly per capita GNI. In general, it is important to note that viral load test prices remain stubbornly high.
PART 4

LEGAL ENVIRONMENT
The main sources of Moroccan law are the Constitution, the Royal Decrees (Dahir) and the legislation passed by Parliament. The Constitution of the Kingdom of Morocco (2011) reaffirms: the right to health as a fundamental right, the right to ‘social protection, medical coverage, and mutualized or state organized social protection’ (Art 31).

The Constitution states other strong principles such as the right of competition and opposes ‘traffic of influence and privileges, abuse of dominance and monopoly, and all other practices contrary to the principles of free and fair competition in economic relations such as those puni-shable by law’ (Art 36). The Constitution recalls the main principles of territorial organization, including the principle of decentralization. In the preamble, the Morocco states its commitment to strengthen and diversify its cooperation with other States, particularly with regard to ‘human, economic, scientific, technical and cultural exchanges with all countries of the world’ and to strengthen South-South cooperation’.

(1) Health as a human right and the right to essential medicine

Health is a fundamental right as set out in the Moroccan Constitution. This right is affirmed in Article 1 of Framework Law 34-09 on the health system and health care provision: ‘The right to protection and health is the responsibility of the state and the society’. Morocco’s subscription to international conventions, including the constitution of World Health Organization, is also recalled in this article. Article 2 states in particular the principles of solidarity, prevention, equality and fairness. The role of associations and NGOs working alongside the state in the field of health is recalled in Art 5. Art 6 sets out the State's responsibility regarding ‘access to pharmaceuticals and essential medicine.’

(2) Care provision organization

Framework Law 34-09 regulates clinics, radiology practices, medical and biological analysis laboratories, which must ‘align with national health strategy and regional health care provision programs. Geographical areas will be delimited where private health facilities will not be allowed to open due to the nature of these institutions and the needs of the population.’ (Art 26). Article 27 states ‘The creation of any advanced or heavy bio-medical equipment installation is subject to compliance with the national health strategy and regional patterns of health care provision, [...]. There shall be established a licensing system for all any such device.’ Furthermore, ‘For profit or non-profit private health institutions which agree to abide by the national health strategy’ are eligible for public-private partnership support (Art 29).

Framework Law 34-09 defines the role of health consultative bodies: ‘To ensure consistency of health system response, to improve governance, and to enable the active participation of response partners, the following bodies will be established: a national health advisory board; a national ethics committee; [...]’ (Art 30).

Minister of Health (MoH) decrees 719-08 and 2-06-656 on hospital organization set the list of hospitals under MoH authority. Payment terms for services and care provided by hospitals and other entities under the MoH’s authority are set in decree 2-99-80.
(3) Decentralization of care provision

The principle of decentralization is set out in Article I of the Constitution of the Kingdom of Morocco: the ‘territorial organization of the Kingdom is decentralized, based on advanced regionalization’. Framework Law 34-09 concerning the health system and the provision of care sets out in detail the decentralization of health services. ‘Care must be provided across the entire national territory in a balanced and equitable manner in accordance with the principles of fairness, equality, and solidarity’ (Art 9).

(4) Main principles of health decentralization.

First, links between the public and the private sector are clearly defined ‘The public sector and the private sector, for profit and non-profit, must be organized in a synergistic manner’ (Art 9). ‘Private health institutions may participate on the basis of specifications to public health actions within the framework of complementarity between the two sectors. In this context, public-private partnership arrangements will be convened to allow private sector participation in public health missions.’ (Art 15)

The national health strategy is then clearly detailed: ‘The national health strategy and regional plans are intended to forecast and foster the change in public and private care provision necessary for an optimal response to population health needs, to achieve harmony and equity in the spatial distribution of material and human resources, to correct regional and intra-regional imbalances, and to harness the growth of supply. ’(Art 20). The national health strategy coordinates care provision across the country within boundaries reflecting service area population and epidemiological, geographical, demographic, socio-economic and administrative needs. ’(Art 22). The national health strategy is established by the authorities after advice from the National Commission for the provision of care ‘for a maximum of 10 years. It must be evaluated every 5 years, and revised if necessary [...]. ’(Art 23).

(5) Screening and biological analysis laboratories

In Art 6, Framework Law 34-09 on health care provision details state responsibility for safety and quality of blood products. Law 03-94 relating to the donation, sampling and use of human blood states ‘Blood submitted for donation must be subject to biological analysis and tested for contagious diseases’ (Art 4).

Routine screening for HCV antibody on all blood donations became mandatory in Morocco from 1995 as set out in decree 2-9420 of 16 November 1995 on public health: ‘Blood submitted for donation must be subject to biological analysis and tested for contagious diseases.’

Unlike HIV, addressed by Royal Decree 554-65 of 17 rebia 1 1387 (26 June 1967) mandating the reporting of certain diseases and prescribing specific preventive measures which reduce the spread of these diseases, HBV and HCV are not subject to mandatory reporting.

Law 12-01 relating to private medical laboratories, such as updated by Dahir 1-02-252 of 02/10/2002, defines a 'medical laboratory' as 'all and any private health institution where tests are done on clinical specimens, understood as samples of biological material, in order to obtain information about the health of a patient as pertaining to the diagnosis, treatment, and prevention of disease.' In section 3, limitations are set: 'medical tests may be performed only upon prescription by a medical doctor or a doctor of dental medicine within the scope of their professional duties, with an exception for repeat tests as prescribed originally by a doctor.'
Health facilities and care providers in the private sector, for profit or not, include: [...] medical laboratories' (Art 14). MoH circular 1078DT/217/SLMSTD, dated 21.09.1989 and updated in 2013, authorizes screening in by non-governmental organizations and resulted in the creation of CIDAGs (free, anonymous information and diagnosis centers).

(6) Medicine and reagents market access regulations

If Law 17-04 dated 22/11/2006 on medicine and pharmacy deals with health products, it does not apply the products consumed in conducting HCV tests, known as reagents, the trade of which is regulated by Law 11-08 law on in vitro diagnostics: 'Are considered "in vitro diagnostic reagent" [...] any chemical or biological substance, presented in individual unit or in kit, specially prepared for in vitro use, either alone or in combination, in biological analysis of samples from the human body, for diagnostic purposes including screening and monitoring.'

Article 2 of Law 17-04 regulates registration and use of reagents in Morocco: 'All and any reagent for use on the market, for commercial purpose or provided free of charge, must be registered with the authorities. This registration is granted for a fixed term, by regulation, on request, to any reagent factory or importer, appropriately declared to the authorities under the provisions of article 6 below. ' Prior to any reagent sale, a technical evaluation of performance will 'review the effectiveness and safety of all physical, chemical or biological reagent'. Are considered registrant any establishment manufacturing or importing reagents for in vitro diagnostic use, appropriately declared to the administration and in whose name the registration is done according to the provisions below: ' There shall be a system of 'reactovigilance' allowing to back-trace any incidents related to reagents after these have been brought to market (Art 11). An advisory board on reagents is established in Article 16: 'There shall be an advisory committee on reagents for in vitro diagnostic use tasked with expressing its opinion on: - reagents registration request or renewals of such. [...] The advisory committee on reagents for in vitro diagnostic use can be consulted by the authorities on any other matter relating to the reagents.' The advisory committee is composed of representatives of: the authorities; hospitals, and the Institut Pasteur du Maroc.[...]' (Art 17).

(7) Public procurement

Framework Law 34-09 pertaining to the health system and the provision of care encourages the 'development and prescription of generic drugs' (Art6). If there are no similar encouragement specific to reagents and diagnostic platforms, Decree 2-12-349 pertains to public procurement, and Law 69-00 on the financial control of the State on public enterprises and other organizations, govern respectively the award of contracts and the budgets of public institutions.

Decree BO 6140, 04.04.2013 on Government Procurement states in its general provisions (Art I) that 'procurement should follow the principles of freedom of access to public procurement; - equal treatment of competitors; - guaranteed rights of competitors; - transparency in the choice of contractor. [...]. These principles ensure the effectiveness of public purchases and the proper use of public funds. They require a prior definition of the needs of the authorities, compliance with open,
competitive tendering requirements, and the selection of the most economically advantageous offer. [...]'.

Law 69-00 dated 11/11/2003 on financial state control over public companies governs oversight of government budgets. The state's financial control is 'exercised over public institutions, companies and undertakings referred to in Article I above, ex-ante and ex-post [...]'. This control aims to, as applicable: - ensure regular monitoring of the management of organizations subject to financial control; - ensure compliance of their economic and financial operations with applicable laws, regulations and statutory provisions; - assess management, economic and financial performance and compliance with missions and objectives assigned to them [...]'.

(8) Intellectual property rights

Intellectual property rights in Morocco are governed by Law 17-97, amended and supplemented by Law 23-13 and Law 31-05. Law 17-97 regulates the various conditions for obtaining title to intellectual property such as patents.23

Morocco is a member of the World Trade Organization (WTO) and as such has signed the TRIPS agreement on 'Trade-Related Aspects of Intellectual Property Rights' which imposes a number of standards, including the obligation to issue patents for a minimum of 20 years.

Morocco has also signed a free trade agreement with the United States which came into force on January 1 2006. This agreement introduced a number of measures which, at the time, were beyond the standard imposed by TRIPS. Specifically, this agreement makes it more difficult to bring generic medicine to market.

As of March 1, 2015, the agreement between Morocco and the European Patent Office took effect and European patent applications may now be validated in Morocco.

(9) Research and technical cooperation

The Constitution of the Kingdom of Morocco in 2011, in its preamble, states the will of Morocco to strengthen and diversify its cooperation with other States, particularly with regard to 'human, economic, scientific, technical and cultural exchanges with all countries of the world and to strengthen South-South cooperation.'

In framework Law 34-09 pertaining to the health system and the provision of care, 'The State encourages and develops research in the field of medicine and medical science.'

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Cited legal texts:

Constitution du Royaume du Maroc, 2011

Décret n° 2-94-285 relatif aux attributions et à l’organisation du ministère de la santé publique

Décret n° 2-06-656 relatif à l’organisation hospitalière

Décret n° 2-9420 du 16/11/1995 relatif à la santé publique

Décret royal n° 554-65 du 26/06/1967 portant loi rendant obligatoire la déclaration de certaines maladies et prescrivant des mesures prophylactiques propres à enrayer ces maladies.

Décret n° 2-12-349 du 8 journada 1434 relatif aux marchés publics (B.O. n° 6140 du 4/04/2013).

Décret n° 2-15-657 pris pour l’application de la loi n°116-12 relative au régime de l’assurance maladie obligatoire de base des étudiants

Décret n° 2-99-80 fixant les modalités de rémunération des services et prestations rendus par les hôpitaux et services relevant du ministère chargé de la santé

Loi cadre n° 34-09 relative au système de santé et à l’offre de soins.

Loi n° 03-94 relative au don, au prélèvement et à l’utilisation du sang humain

Loi n° 12-01 relative aux laboratoires privés d’analyses de biologie médicale tel qu’actualisée par le dahir n°1-02-252 du 02/10/2002


Loi n° 65-00 portant code de la couverture médicale de base

Loi n° 116-12 relative au régime de l’assurance maladie obligatoire de base des étudiants

Loi 11-08 relative aux réactifs de diagnostic in vitro

Loi n°17-04 portant code du médicament et de la pharmacie (22/11/2006)

Loi n°17-97 relative à la propriété intellectuelle (modifiée et complétée par les lois : 23-13 et 31-05)

Loi n°104-12 relative à la liberté des prix et de la concurrence (30/06/2014)


Circulaire ministérielle n° 55/DELM/34 du 26/07/2013

Arrêté du ministre de la santé n° 719-08 fixant la liste des hôpitaux relevant du ministère de la santé
Recommendations

The implementation of the National Strategic Plan without delay

Morocco’s response to HCV includes the best Direct Acting Antivirals, locally produced, and an ambitious five-year National Strategic Plan (NSP) which takes into account all recent World Health Organization recommendations.

The NSP should be launched as soon as possible to provide everyone with access to pan-genotypic HCV treatment. Peg-interferon prescriptions should immediately cease. People in need of it should immediately be provided with access to the best biological monitoring possible.

The rolling-out of national HCV screening & prevention campaign

Targeted prevention campaigns for key populations must be implemented to identify as quickly as possible those in need of treatment. Regulatory approval and widespread use of HCV rapid tests should be realized to identify as many people requiring treatment as quickly as possible.

The immediate implementation of free access to treatment

Access to HCV diagnostics should be made free for the entire population without delay, that is to say, regardless of the launch of the NSP, and there should be a reduction in upfront ‘out-of-pocket’ costs related to care. Ancillary costs for tests incurred by people living with HCV—such as gastroenterologist consultations, hospital stays, travel and opportunity costs—are so high that, even if the treatment is free, these upfront costs to the patient, despite full or partial refunds, create obstacles for those in need of care and for the Ministry of Health’s target of HCV elimination by 2030. These additional costs should therefore also be covered.

Effective decentralization of HCV response

Decentralization should be strengthened with the establishment of HCV-specialized referral centers across Morocco, and the establishment of referral centers in regions such as Quarzazate, Laayoune & Dakhla.
**Review blood sampling and samples routing**

The process of blood sampling and transport of samples to referral centers must be reviewed, as must the planification of the reagent required for theses tests. To this end, stakeholders in the national response to hepatitis, tuberculosis and HIV should be consulted as viral load tests are often performed on the same machines.

**The process of blood sampling and transport of samples to referral centers must be reviewed.**

Pooled purchases, expanded human resources, and improved sampling and transportation of samples to referral centers can only be beneficial as it allows for better performance of available platforms, better use of human resources, and more effective coordination of national responses towards their respective targets.

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**The implementation of new procurement strategy for reagents**

- Prices charged by Abbott, Roche and Cepheid on the Moroccan market are very similar, illustrating the quasi monopoly which these three manufacturers currently enjoy in Morocco. Through the Global Fund’s Pooled Procurement Mechanism, Morocco is entitled to a 50% discount from Roche but does not yet exercise it, thereby paying twice what it should. If Morocco chooses to continue using Roche platforms, Morocco must be allowed to purchase at the discount rate.

- The Global Fund’s new central purchasing platform, Wambo, should have its scope expanded to cover diseases (other than AIDS, tuberculosis and malaria), at least for HIV co-infection. This would allow Morocco to access centrally purchased reagents at prices close to those proposed under these special programs ($10).

Wambo was contacted but did not respond to our questions on this matter.

- More generally, maintaining Abbott, Roche and Cepheid in a situation of monopoly will have no positive impact on test prices, a key bottleneck in any national epidemic response, which is why Morocco must opt for open platforms rather than current proprietary test platforms. Open platforms accept reagents from a much wider variety of suppliers, therefore ensuring stronger competition and lower prices. As closed platforms induce systematically higher operating costs, Morocco must immediately opt to equip its HCV response with open platforms to foster competition, reduce costs, and provide leverage in price renegotiations with Abbott, Roche and Cepheid.
Foster local production and reduce imports

- Today, the high-tech platforms required to measure HVC damage (FibroTest®, Fibroscan®), viral load test, and genotyping are available exclusively through a handful of companies which benefit handsomely from their respective monopolies. In 2011, the WHO recommended local production and technology transfer in the field. WHO urged countries to follow the examples of other countries which have tried to develop their domestic production. This is the case of Brazil, as part of a wider policy to produce locally most health products to provide population with wide access to health care while limiting imports. This policy, driven by national laboratories Farmanguinhos, Fiocruz and Biomanguinhos, has enabled the development of various health products. The objective is not only to lower prices in the short term but also to develop local production based on local public health needs and limit dependence on a few firms enjoying a monopoly and therefore having the ability to almost unilaterally fix prices. WHO therefore invited countries to follow the Brazilian example. In the context of South-South cooperation advocated in Morocco’s Constitution of 2011, Morocco could learn from the Brazilian example.

- Comprehensive mapping of existing patents in Morocco on the various components of platforms for viral load testing is also necessary to confirm or deny absence of intellectual property barrier. But the expiration, that has been observed, on most of these patents confirms that the less relevant strategy for local producers might be the resort to technology transfers, as those tie originator and patent holder producers to the other producers willing to produce these technologies, thus expending their monopoly beyond the patent term. By itself, the expiration of patents should allow any producer willing to do so to develop the technologies, either thanks to the disclosed information in the patent application, or by reverse engineering.

- Know-how and strategies exchange could take place between Biomanguinhos, or open platform producers such as Biocentric, and Moroccan investors and authorities (Ministry of Industry and Technology, Ministry of Health) as recommended by WHO.

- Simultaneously, stakeholders in the HCV response could gather at the national level to consider long-term local production strategies. Discussion could focus on medicines, reagents, vaccines, open diagnostics platforms, but also on non-invasive advanced hepatic score platforms used to measure liver damage.
Ending the monopoly on non-invasive liver fibrosis assessment

Regarding the care protocol, access to the most accurate non-invasive methods for assessing liver fibrosis must be universal as these are much less risky than previously-used invasive Percutaneous Liver Biopsies and provide more accurate results than APRI or FIB-4 scores.

The issue with FibroTest® and FibroScan® lies in the fact that these technologies are in the hands of two firms, taking advantage of a perfect world monopoly. Not only were patents filed, which is a barrier, but also the know-how necessary for the development of such platforms would take years for others to independently develop the technology. Echosens and BioPredictive therefore enjoy a perfect monopoly without fear of competition. Directly contacted for this report, the presidents of each firm closed the door for collaboration with other firms to transfer technology and provide greater access, including in resource-limited countries such as Morocco. Yet it is important to remember that these technologies have been developed as part of French public research (INSERM, AP-HP, ESPCI).

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<table>
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<th>Research funded and conducted in a public structure</th>
<th>Discovery patented in the name of the inventor or the public institution</th>
<th>Exclusive marketing license granted to a private firm</th>
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CURRENT MODEL (example of FibroTest & FibroScan)  
LONDEIX P. (ALCS 2017)

- Regarding FibroTest®, AP-HP and INSERM must revoke the exclusive license granted to BioPredictive and instead grant open licenses, including to Moroccan producers, and conduct technology transfer with them.

- Regarding FibroScan®, Echosens, which was developed as part of the ESPCI, owns the patents on the technology. Funded by the French taxpayer, INSERM and the ESPCI must take a position in favor of technology transfer to the countries and companies of the public and private sectors which need it because Echosens and BioPredictive’s respective monopolies have serious consequences worldwide for people living with HCV.
What the UN High-Level Panel on Access to Medicines report says

Open models of innovation, which are generally patent-free and often rely on quick, straightforward licensing, have been successful, particularly in the early phase of biomedical research. In this model, partners work collaboratively, driving new fields of science and expanding the knowledge base for all, thereby hastening progress towards the development of medical tools. Such partnerships can be between and among industry partners or as part of public-private partnerships. Collaborating on precompetitive activities, for example, can help solve thorny technical challenges, better understand the aetiology of disease, validate potential novel medicine targets or identify biomarkers to ascertain if a health technology is working. This open model is especially important to lower the hurdles of entry and accelerate the pace of development of health technologies, including those needed to combat emergent diseases.

For the public to reap the full benefit of the public investment in research, public funding agencies must ensure that, when feasible, data, results and knowledge generated from such public investment be made broadly available. Such availability might be achieved, for example, through strong, enforceable policies on data sharing and data access that are a condition of grant awards, by creating data repositories and by establishing normative data standards that can be adopted and used by the biomedical community. In all cases, public funding agencies should strongly encourage patenting and licensing practices that benefit public health, including the use of non-exclusive licences, donation of intellectual property rights, participation in public sector patent pools and other mechanisms that can maximize innovation while promoting access.

In the context of licenses with implications for resource-limited settings, public health-sensitive provisions for the management of intellectual property deriving from publicly-funded research (sometimes referred to as global access licensing provisions) can be pursued. Over the past two decades, some universities and public funding institutions have begun to explore and put such provisions and frameworks into place. These provisions seek to promote tech-
technology transfer and access by requiring differentiated licensing terms and conditions according to a number of factors such as geography, income, manufacturing and distribution costs, among others.

**Intellectual property & Health products' patents: exercise caution with trade agreements**

- Morocco signed a free trade agreement with the United States more than ten years ago, which modified Moroccan law on intellectual property. Morocco is currently negotiating a Deep and Comprehensive Free Trade Agreement ("ALECA") with the European Union. The impact study carried out recently by researchers in Brazil on the draft EU/MERCOSUR agreement with the South American common market has shown this agreement would have dramatic consequences on prices of medicines and health products. This agreement could affect the price of HCV screening and access to medicines in general, this is why "ALECA" should not be signed by Morocco.

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Acronyms

AMO : Mandatory Health Insurance
ANRS : Agence nationale de recherche sur le sida (France)
AP-HP : Public Hospitals of Paris
APRI : Aminotransferase-to-Platelet Ratio Index
BMS : Bristol Myers Squibb
CHP : Provincial Hospital
CHR : Regional Hospital
CHU : Centre Hospitalier Universitaire teaching hospital
CNOPS : Public sector social insurance trust fund
CHP : Centre Hospitalier Provincial
CHR : Centre Hospitalier Régional
CHU : Centre Hospitalier Universitaire
CNOPS : Public sector social insurance trust fund
CNSS : Private sector employees social insurance trust fund
DAA: Direct Acting Antivirals
DCFTA : Deep and Comprehensive Free Trade Agreement (EU/Morocco)
DELM : Direction de l’Épidémiologie et de lutte contre les Maladies
EC : Marking (European Union non-toxicity certification
EMRO : WHO Regional Office for the Eastern Mediterranean
ESPCI : Ecole Supérieure de Physique et de Chimie Industrielles de la ville de Paris
FDA : The Food and Drug Administration of the USA
GFATM : aka the Global Fund against AIDS, Tuberculosis and Malaria
GNI : Gross National Income
HBV : Hepatitis B Virus
HCV : Hepatitis C Virus
HIV : Human Immunodeficiency Virus
IDU : Injecting Drug Users
IMF : International Monetary Fund
INH : Institut National d’Hygiène
INSERM : Institut National de la Santé et de la Recherche (France)
IPM : Institut Pasteur du Maroc
LMIC : Lower middle income country (middle income countries of the lower bracket)
    - World Bank
MENA : The Middle East North Africa region
MIC : Middle Income Countries
NGO : Non Governmental Organization
PPM : Pooled Procurement Mechanism
RAMED : National medical coverage plan for the most vulnerable
RNA : Ribonucleic acid
STI : Sexually Transmitted Infection
SUS : Sistema Unico de Saúde
SVR : Sustained virological response
UMIC : Upper middle income country (middle income countries of the upper bracket)
    - World Bank
VL : Viral load (viral load testing)
WHO : World Health Organization
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