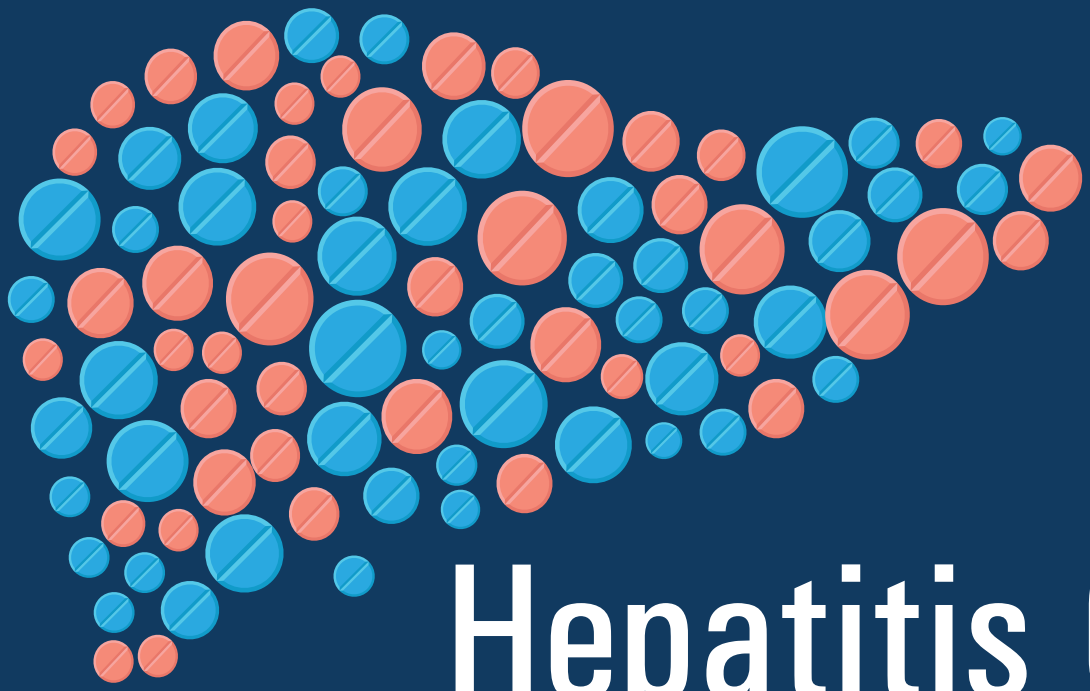
CLINTON HEALTH ACCESS INITIATIVE



Hepatitis C

Market Report

Issue 1 • May 2020

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Disclaimer: The data sources primarily used for analysis in the report include the India Import Export data, CHAI country teams, Ministry of Health counterparts, stakeholder (WHO, UNPD, and NGO and civil society partners, such as FIND, World Hepatitis Alliance, etc.) conversations, and regulatory information provided by drug suppliers. CHAI has taken precautions to verify the information shared on the report. However, the analysis in the report is not exhaustive, and the responsibility for the interpretation and use of the material lies with the reader. The mention of specific companies or supplier products does not imply that CHAI is endorsing or recommending them.

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Acronyms

ARV	Antiretroviral
ART	Antiretroviral Therapy
BE	Bioequivalence
CHAI	Clinton Health Access Initiative Inc.
CO	Country Office
CPT	Carriage Paid To
CRP	Collaborative Registration Procedure
CT/NG	Chlamydia trachomatis/Neisseria gonorrhea
CY	Calendar Year
DAA	Direct-Acting Antivirals
DAP	Delivery At Place
DCV	Daclatasvir
EID	Early Infant Diagnosis
ERP	Expert Review Panel
FDC	Fixed Dose Combination
FDF	Finished Dosage Form
FOB	Freight On Board
FPP	Finished Pharmaceutical Product
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GHSS	Global Health Sector Strategy
G/P	Glecaprevir/Pibrentasvir (Fixed Dose Combination)
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IA	Immunoassay
LDV	Ledipasvir
LMIC	Low-and Middle-Income Country
MoH	Ministry of Health
MPP	Medicines Patent Pool
MTB	Mycobacterium Tuberculosis
NAT	Nucleic Acid Test
PAHO	Pan American Health Organization
PCR	Polymerase Chain Reaction
PPM	Pooled Procurement Mechanism
QA	Quality Assured
RBV	Ribavirin
RDT	Rapid Diagnostic Test
RNA	Ribonucleic Acid
SOF	Sofosbuvir
SOF/DCV	Sofosbuvir/Daclatasvir (Fixed Dose Combination)
SOF + DCV	Individual Sofosbuvir and Daclatasvir Combined
SOF/LDV	Sofosbuvir/Ledipasvir (Fixed Dose Combination)
SOF/VEL	Sofosbuvir/Velpatasvir (Fixed Dose Combination)
SRA	Stringent Regulatory Authority
SVR12	Sustained Virologic Response at week 12
VEL	Velpatasvir
VL	Viral Load
WHO PQ'd	World Health Organization Prequalified

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Key Takeaways

DIAGNOSTICS

1

The World Health Organization (WHO) now recommends a simplified diagnostics algorithm for HCV. The current algorithm includes HCV antibody screening, confirmation of viremia by Viral Load (VL), and confirmation of cure by VL at week 12 post-treatment (SVR12). The previous guidance for genotyping and week four monitoring has been removed.

2

The use of quality assured (QA) diagnostic products, which are Stringent Regulatory Authority (SRA) approved or WHO Prequalified (PQ'd), is important to maintain a high standard of care. Procurement agents are encouraged to assure the quality of products under consideration.

3

Diagnostic pricing often contains complex individual cost components, which may be challenging to ascertain. Price visibility is essential to identify opportunities for cost reductions and to assure the cost-effective growth of public programs.

4

Inclusive pricing offers a set price and aggregates specific cost components for more streamlined procurement.

5

Current diagnostic pricing within public programs varies broadly with some countries achieving low prices (illustrated in Exhibits 7 and 8) which can serve as a benchmark for other programs.

TREATMENT

1. Countries can seek opportunities to accelerate registration/time limited import approval of WHO prequalified/ERP reviewed products to ensure product availability, supply security, and access to affordable prices by fostering competition.

2. India, Egypt, Pakistan, Rwanda are examples of countries that have committed to scaling up their HCV programs. To accelerate progress towards HCV elimination, countries will need to intensify case finding efforts. Countries that prioritized patients who were previously diagnosed and awaiting care for HCV treatment will need to focus on active case finding.

3. Several other countries are expanding their HCV treatment programs, but the overall progress toward achieving WHO elimination goals by 2030 is slow. Low- and Middle-Income Countries (LMICs) can now aim to achieve a price of under US$100 per patient course for 12 weeks of treatment with WHO PQ'd Sofosbuvir (SOF) and Daclatasvir (DCV). LMICs with a procurement plan, large procurement volumes and strong public commitment by government to HCV elimination over a defined period of time can further aim for US$60 per patient course for 12 weeks of treatment with WHO PQ'd SOF and DCV, as observed in Rwanda.

4. Limited data on in-country DAA procurement and procurement budgets has restricted capability to predict future market trends for DAAs. Transparency on in-country procurement plans can help identify future demand for DAAs.

5. The global benchmark prices for drugs have declined significantly (illustrated in Exhibit 12); however, several countries continue to pay substantially higher prices.

6. Countries can explore global procurement mechanisms such as the United Nations Development Program (UNDP) health procurement mechanism, the Global Fund Pooled Procurement Mechanism (PPM), and the Pan American Health Organization's (PAHO) Strategic Fund to procure HCV treatment at more affordable prices. Global procurement mechanism benchmark prices may also be used by countries as reference prices for local tenders, or for negotiating in-country prices with suppliers.

7. Countries can explore alternative pricing mechanisms such as public-private partnerships and insurance schemes in order to reduce the financial burden on patients paying out-of-pocket.

8. Countries observing high price mark-ups can reduce prices by identifying different contributing factors and limiting them where possible.

9. Countries can benefit from lower pricing by planning procurement and ordering DAAs in optimal quantities and/or publicly committing to HCV program scale-up toward elimination.

Key Statistics

Global HCV Burden and Progress

71 million people living with chronic HCV globally — 2015

399K deaths from HCV — 2016

13.1 million people

19% know their HCV status — 2017

5 million people

7% received treatment for HCV infection — 2017

HCV Elimination Goals

WHO Global Health Sector Strategy (GHSS) on viral hepatitis calls for the elimination of HCV as a public health threat by 2030

THE GOAL IS TO ACHIEVE

10% reduction in number of hepatitis-related **deaths** by 2020

65% reduction by **2030**

30% reduction of new hepatitis-related **infections** by 2020

90% reduction by **2030**

Lowest available market prices for WHO PQ'd diagnostics and drugs

Pricing for quality assured products is lowest in Rwanda among high-burden LMICs

Pricing breakdown in Rwanda:

RDT $0.75 + VL test $9.36 + Treatment price $60* + SVR12 test $9.36 = $79.47/ patient cure

***$60/patient course** [For 12 weeks of treatment with SOF and DCV]

The Global Fund Pooled Procurement Mechanism Price Benchmarks for Drugs

$79/patient course *for* **12 weeks with SOF/DCV FDC**

$94/patient course *for* **12 weeks with individual SOF + DCV**

Introduction

Approximately 71 million people worldwide (as of 2015) are chronically infected with HCV, one of the world's most prevalent infectious diseases.[1] More than 80 percent of the burden is in LMICs.[2] The HCV epidemic continues to grow both in size, with 1.75 million new infections annually, and in severity, causing more than 400,000 deaths per year from advanced liver disease, including cancer.[3] Despite its high prevalence, morbidity and mortality, only 19 percent (~13.1 million) of people living with HCV knew their status in 2017[4], and only 7 percent (~5 million) received treatment worldwide as of 2017.[5] Many factors contribute to this major gap in access, including limited awareness due to the asymptomatic nature of HCV infection, lack of funding and infrastructure for public screening and treatment programs, and the historically high costs of previous treatments (interferon-based) that had high toxicities and low success rates.

WHO and its member states committed in 2016 to eliminate viral hepatitis by 2030. The availability and pricing of pan-genotypic DAAs with cure rates over 95 percent and minimal side effects, coupled with a simple diagnostic algorithm, make the goal of achieving HCV elimination by 2030 feasible.

Although uptake has been uneven across LMICs and scale up has been concentrated in few countries, declining costs for diagnosis and treatment have resulted in increases in the number of patients initiated on treatment. In turn, increasingly affordable and effective diagnostic tools and medications are enabling the simplification and decentralization of HCV diagnosis and treatment services, supporting further scale-up of services. HCV screening and diagnosis using existing technologies is feasible and the cost of testing continues to decline. A number of inexpensive and robust Quality Assured (QA) tests are available for screening and confirmation of viremia including rapid antibody tests and laboratory-based and near point-of-care VL diagnostics.

The introduction of DAAs in the market in 2014 has been a game changer for HCV treatment. DAAs are significantly superior to interferon-based treatment in several aspects. Depending on the regimen used, DAAs are pan-genotypic, have high cure rates (over 95 percent) with minimal side effects, and are orally administered over eight to 12 weeks. Since 2014, the cost of treating HCV in LMICs has come down significantly from over US$3,000 per patient course with interferon-based treatment (before the introduction of DAAs) to as low as US$60 per patient course in 2019 with WHO PQ'd individual SOF and DCV (SOF + DCV) in Rwanda.

While the number of people who initiated DAA-based treatment for HCV rose between 2015 and

[1] Polaris Observatory HCV Collaborators. Global prevalence and genotype distribution of hepatitis C virus infection in 2015: a modelling study. Lancet Gastroenterol Hepatol 2017.

[2] Polaris Observatory HCV Collaborators. Global prevalence and genotype distribution of hepatitis C virus infection in 2015: a modelling study. Lancet Gastroenterol Hepatol 2017.

[3] WHO global health estimates for 2015 published in 2016 (Global Health Estimates 2015: deaths by cause, age, sex, by country and by region, 2000–2015.); 2016.

[4] WHO Progress report on HIV, viral hepatitis and sexually transmitted infections; 2019.

[5] Web Annex 1. Key data at a glance. In: Progress report on HIV, viral hepatitis and sexually transmitted infections 2019. Accountability for the global health sector strategies, 2016–2021. Geneva: World Health Organization; 2019.

2016 from approximately one million to one and a half million, only a few countries such as India, Egypt and Pakistan were responsible for the bulk of that increase. Patients in Egypt and Pakistan accounted for about half the patients who started DAA treatment in 2016.[6] Uptake of DAAs has been limited across several high-burden LMICs and challenges to access continue to exist. Some of these market challenges include lack of awareness among stakeholders on global benchmark pricing, availability of WHO PQ'd product options in-country, slow or limited in-country product registration, and limited domestic and donor financing. As a result, volumes of patients put on treatment have not increased in proportion to the decline in price of DAAs.

Similar challenges also exist for diagnostics. Global targets for viral hepatitis elimination are predicated on achieving widespread diagnosis of the majority of persons living with chronic viral hepatitis. Implementing reliable and affordable testing in LMICs is essential to enable the successful use of DAAs in treatment. However, despite substantial global price reductions, the cost of diagnostics remains high in many countries, with drivers ranging from fragmented demand, limited in-country registrations, high mark-ups and non-coordinated procurement. Furthermore, there are significant gaps in publicly available information for the global diagnostics market in the areas of pricing, test volumes and in-country registrations.

Taking into account market challenges on the treatment and diagnostics front, there is a risk that countries may not reach the WHO endorsed Global Health Sector Strategy (GHSS) HCV elimination goal by 2030. Better market transparency for key stakeholders, including governments, suppliers, and donors, could be a step toward mitigating these market challenges.

The aim of this HCV market report is to provide an overview of supplier landscape for WHO PQ'd/ ERP reviewed HCV treatment drugs and diagnostics, outline historical volumes and pricing trends, highlight global benchmark prices, and suggest potential ways in which countries can access diagnostics and drugs at more affordable prices.

The report focuses on LMICs with a high HCV burden, and WHO PQ'd/ ERP reviewed products as they meet quality assurance standards and have been declared bioequivalent to the innovator products. While the report does not advocate the use of locally approved products, pricing information on the report accounts for locally approved products (which do not meet global quality standards but meet local quality standards), in addition to WHO PQ'd/ERP reviewed products, as these products are available and being used in several LMICs.

A concise report on historical pricing and volume trends will help the broader HCV community to understand the market landscape, identify existing gaps, and work toward solving demand and supply related problems in the market. Addressing the market related problems can help expedite progress in achieving HCV elimination by 2030.

Impact of COVID-19 Pandemic on Hepatitis C Elimination

As significant public health resources are redirected to address the COVID-19 pandemic, the strain on systems being pushed beyond limits to support pandemic preparedness and response is having critical implications on global health programs. Policies in place on physical distancing and redirected efforts of Ministries of Health and healthcare workers is affecting HCV diagnosis, treatment and harm reduction programs to varying degrees across countries. For the most part, countries are suspending routine screening, screening campaigns and clinic visits, which is disrupting HCV case finding efforts. There is a risk of incidence of HCV increasing with closure of harm reduction centers, without having policies in place to ensure that people who inject drugs that are at high risk of HCV infection have alternative access to critical harm reductions services, such as needle and syringe programs and opioid substitution therapy. Furthermore, the temporary closure of healthcare facilities and limits to non-emergency visits to reduce risk of SARS-CoV-2 virus transmission is affecting HCV treatment uptake.

The world is facing an unprecedented pandemic crisis in COVID-19. The responses to the pandemic must also ensure that momentum in the scale-up of HCV elimination programs and other health priorities is not lost. Global and country action towards controlling COVID-19 can reinforce the fight against other epidemics; COVID-19 investments, for example, in the expansion of diagnostic capacity, supply chain systems, and upskilling of healthcare workers can lay the foundation for an acceleration of efforts to strengthen health systems overall. These opportunities cannot be overshadowed by the overwhelming challenges the world is facing.

[6] WHO Progress Report on Access to Hepatitis C Treatment; Mar 2018.

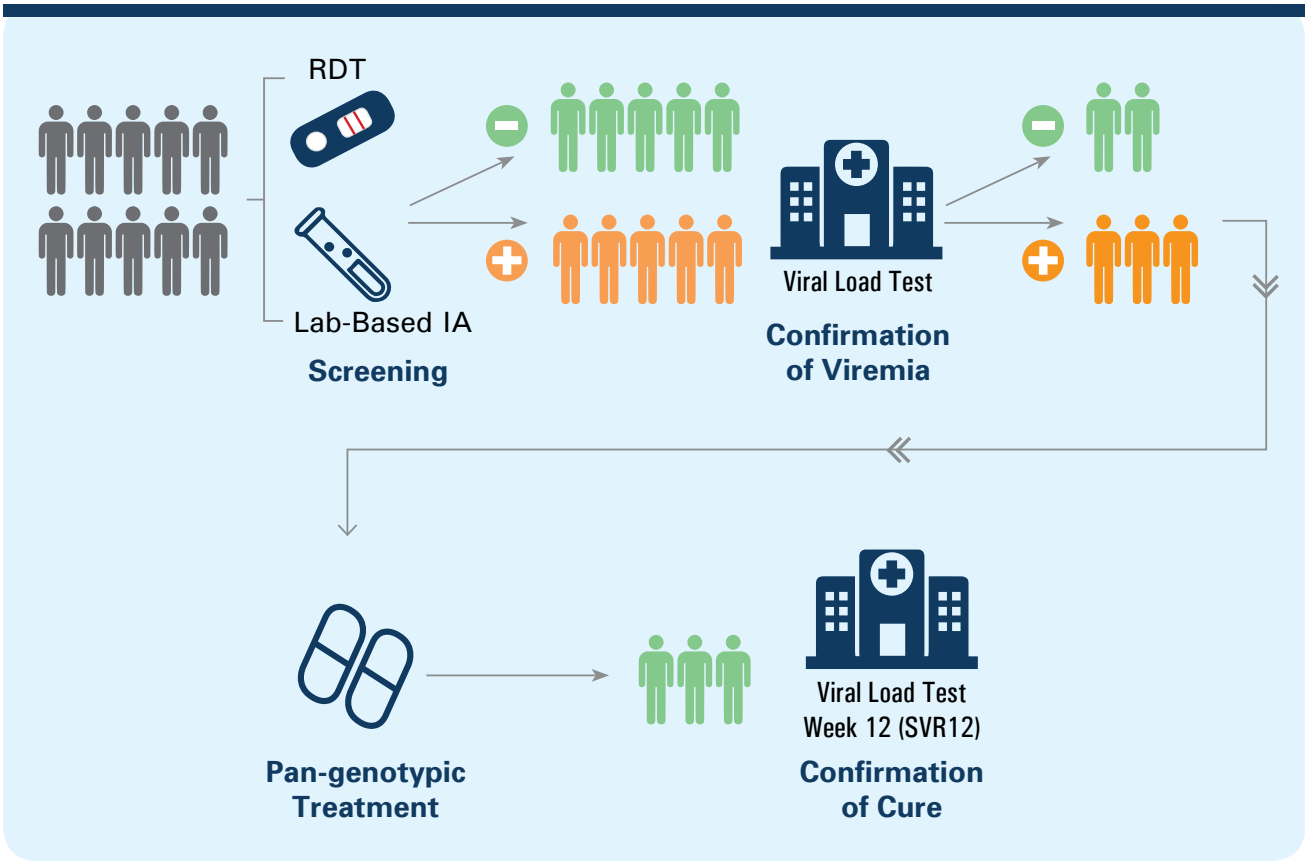
World Health Organization Recommended HCV Testing and Treatment Algorithm

Diagnostics Algorithm

A health worker prepares samples for HCV testing at a lab in Rwanda *© Christine McNab*

The WHO recommends a simplified, two-step algorithm to diagnose HCV. The algorithm includes an antibody screening test followed by a VL test for confirmation of viremia.[7] All those who test positive for VL should be referred for treatment regardless of disease stage, though the duration of treatment may differ depending on the presence of cirrhosis. Twelve weeks after completing treatment, a VL test for confirmation of cure is recommended (SVR12).

Exhibit 1: Who Recommended Hcv Diagnostics Cascade for Adults[7]



Recommended prior to treatment:	No longer necessary:
Assessment of hepatic fibrosis by APRI or FIB-4. Assessment of co-morbidities, pregnancy, and potential drug-drug interactions. Genotyping for adolescents (12-17 years) to determine the appropriate treatment regimen.	Genotyping for adults when pan-genotypic DAAs are used in treatment. HCV viral load at week four due to a lack of clinical evidence in predicting cure.

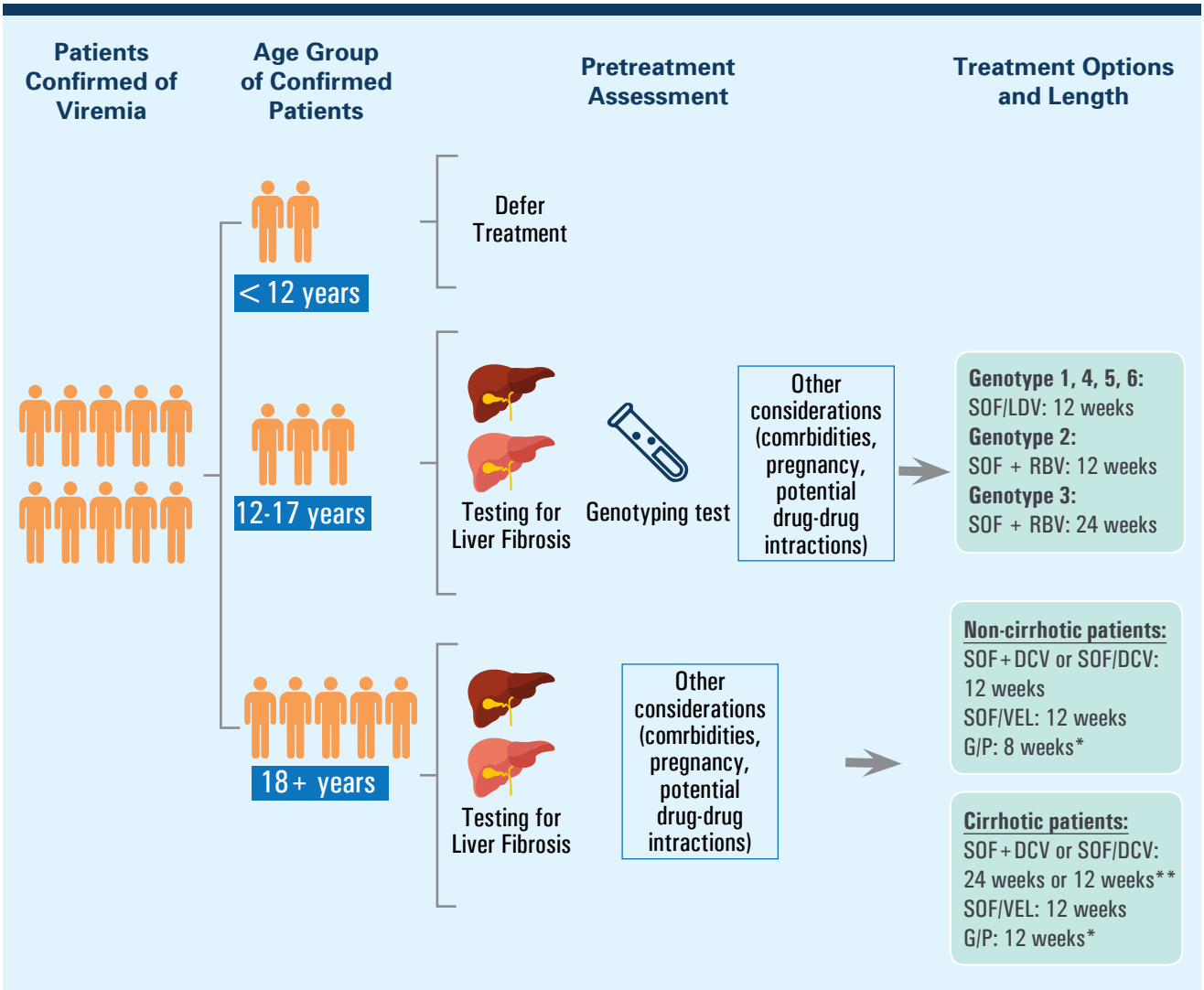
[7] Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection, World Health Organization (WHO); July 2018.

Treatment Algorithm

Treatment for Adults (18 years or older)

For adults, WHO recommends pan-genotypic regimens including SOF with DCV [SOF + DCV or SOF/DCV Fixed Dose Combination (FDC)], Sofosbuvir/Velpatasvir (SOF/VEL) or Glecapravir/Pibrentasvir (G/P) as potential options for treatment. As per WHO guidelines, genotyping is not required for adults prior to treatment initiation, but continues to be recommended for adolescents (aged 12–17 years) when a non-pan-genotypic regimen is used. In the near future it is anticipated that pan-genotypic regimens will be approved for younger age bands, abrogating the need for genotype testing in these groups. Further, factors such as the level of liver fibrosis (identified through aspartate-to-platelet ratio index), comorbidities, pregnancy, and potential drug interactions should be considered while identifying the desired treatment regimen and length of treatment (refer to Exhibit 2 for details).

Exhibit 2: WHO Recommended HCV Treatment Cascade, 2018



** Persons with HCV genotype 3 infection who have received interferon and/or ribavirin in the past should be treated for 16 weeks; US guidelines now recommend 8-week treatment for cirrhotic and non-cirrhotic patients.*

*** May be considered in countries where genotype distribution is known and genotype 3 prevalence is <5%.*

Details on treatment recommendation and algorithm for adolescents and children available in Appendix 1.

Source: WHO Guidelines for the Care and Treatment of Persons Diagnosed with Chronic Hepatitis C Virus Infection, 2018.

SOF with DCV is the most commonly used DAA combination for HCV treatment for adults across LMICs as it is pan-genotypic, has equally efficacious treatment outcomes as other pan-genotypic DAAs, is more affordable, and there are multiple QA generic suppliers manufacturing SOF and DCV. The other pan-genotypic drugs recommended by the WHO include SOF/VEL and G/P, however, their uptake has been limited in LMICs due to their higher price and/ or lack of WHO PQ'd generic options available (refer to 'Supplier Landscape' section to identify WHO PQ'd options for key DAAs). A new regimen will have to be price competitive with SOF + DCV or SOF/DCV FDC or significantly clinically superior (for example, shorter duration of treatment, larger age groups that the treatment can be administered to etc.) for it to be prioritized in LMICs. SOF/LDV, and SOF + RBV are not recommended for adults as they are genotype-specific. Exhibit 3 shows the key HCV treatment regimens and WHO's treatment recommendations.

SOF with DCV is the most commonly used DAA combination for

HCV treatment for adults

across LMICs

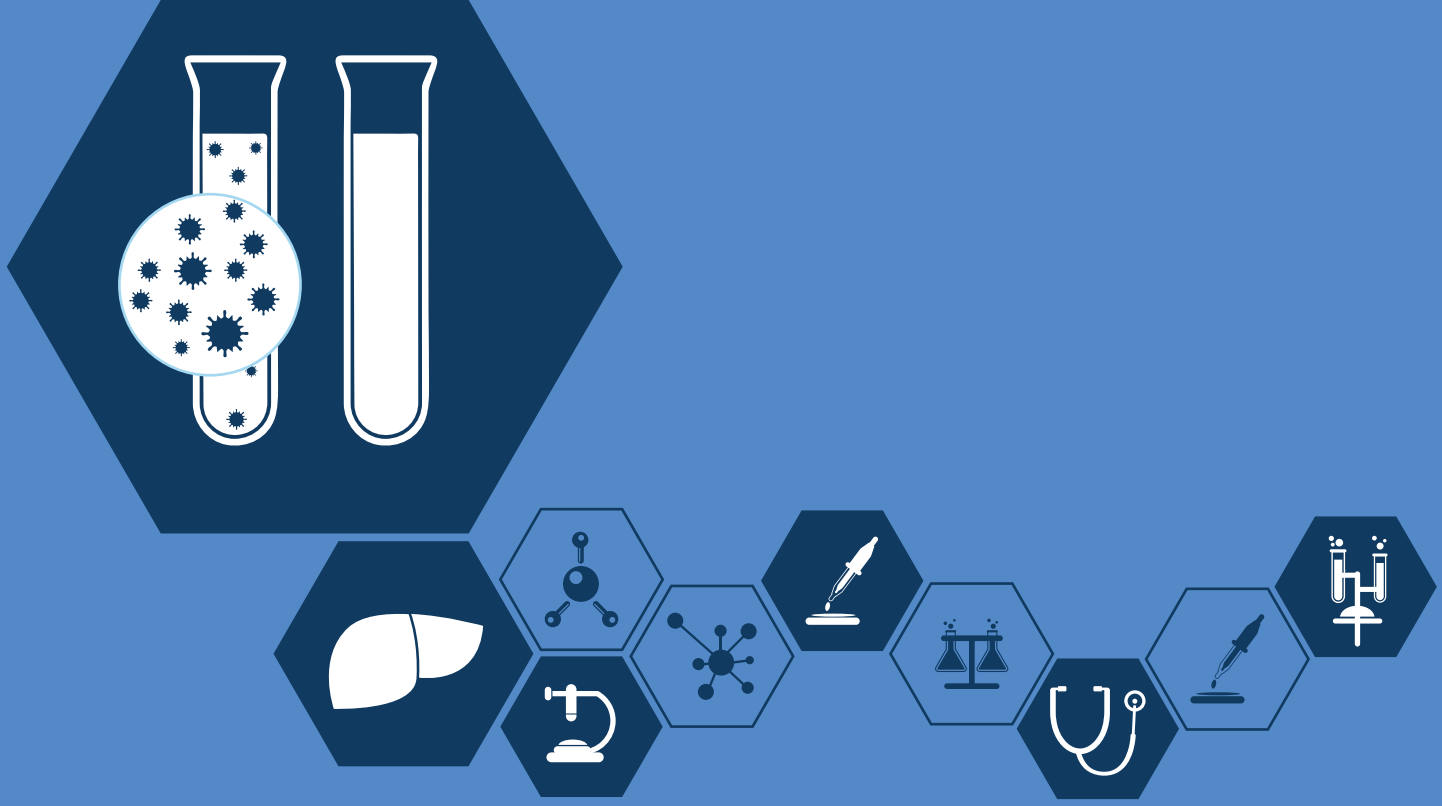
Exhibit 3: World Health Organization Recommended Regimens for HCV Treatment

	Regimens				
	Regimens for use in adults (Aged 18 years and above)			Regimens for use in adolescents (Aged 12-17 years)	
	Sofosbuvir/ Velpatasvir (SOF/VEL)	Sofosbuvir/ Daclatasvir or Sofosbuvir + Daclatasvir (SOF/DCV FDC or SOF + DCV)	Glecaprevir/ Pibrentasvir (G/P)	Sofosbuvir/Ledipasvir (SOF/LDV)	Sofosbuvir + Ribavirin (SOF + RBV)
Efficacy in infection with HCV genotypes 1–6	Pan-genotypic	Pan-genotypic	Pan-genotypic	Genotype dependent (Genotypes 1,4,5,6)	Genotype dependent (Genotypes 2 and 3)

KEY TAKEAWAY

The WHO HCV testing and treatment algorithm recommends the following:

- Offering treatment to all individuals diagnosed with HCV infection who are 12 years of age or older, irrespective of disease stage
- Pan-genotypic regimens for all adults. No pre-treatment genotype testing required for the following regimens: SOF/DCV FDC or individual SOF + DCV, SOF/VEL, and G/P
- Genotype-specific regimens for children aged 12-17 years
- Deferral of treatment for children aged less than 12 years



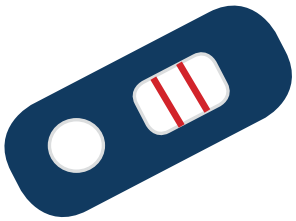
HCV DIAGNOSTICS

Supplier Landscape

Advantages of Quality Assured Rapid Screening Tests

The use of tests of unverified quality should be avoided. The use of SRA approved or WHO PQ'd diagnostics is recommended to ensure high-quality results. Although many screening programs continue to utilize lab-based immunoassays, Rapid Diagnostic Tests (RDTs) have become widely available at affordable prices. RDTs enable identification of antibody positive individuals in as little as five minutes from a drop of blood obtained by a finger stick. These rapid tests have potential advantages over lab-based immunoassays for screening. The use of RDTs:

- Enables decentralized screening
- Mitigates the challenges of sample collection and transportation
- Enables results to be returned immediately, thereby avoiding the need for subsequent appointments with potential loss to follow-up



RDTs enable identification of antibody positive

individuals in as little as five minutes from a drop of blood obtained by a finger stick.[8]

[8] WHO Prequalification of In Vitro Diagnostics, Public Report, SD BIOLINE HCVWHO ref: PQDx 0257-012-00.

Exhibit 4 illustrates a list of WHO PQ'd rapid antibody tests and lab-based immunoassays.

Exhibit 4: WHO prequalified rapid and lab-based immunoassays

Rapid Antibody Tests		
Product Name	**Manufacturer**	**Sample Type**
Rapid Anti-HCV	Intec Products	Serum, Plasma, Whole Blood
SD BIOLINE HCV	Standard Diagnostics	Serum, Plasma, Whole Blood
OraQuick HCV Rapid Antibody	OraSure Technologies	Whole Blood
STANDARD Q HCV Ab	SD Biosensor	Serum, Plasma, Whole Blood
Lab-based Immunoassays		
Product Name	**Manufacturer**	**Sample Type**
ARCHITECT HCV Ag	Denka Seiken (Abbott)	Serum, Plasma
INNOTEST HCV Ab IV	Fujirebio Europe	Serum, Plasma
INNO-LIA HCV Score	Fujirebio Europe	Serum, Plasma
Murex anti-HCV	DiaSorin South Africa	Serum, Plasma
Bioelisa HCV 4.0	Biokit South Africa	Serum, Plasma
MONOLISA HCV Ag-Ab ULTRA V2	Bio-Rad	Serum, Plasma

Quality Assured Screening Tests

As shown in Exhibit 4, four RDTs have been WHO PQ'd. The inclusion of Intec in 2019 is significant as it is priced competitively, at approximately US$1, in line with the SD BIOLINE HCV RDT from Abbott. The OraQuick RDT from Orasure continues to be priced at US$6-8, making it largely uncompetitive in LMICs.[9] The Abbott ARCHITECT core antigen (cAg) test is unique among the PQ'd lab-based immunoassays in that it may be used to confirm active viremia when nucleic acid VL testing is not available. It should be noted, however, that cAg is not recommended for SVR12.

Given the large number of rapid antibody and lab-based immunoassays on the market, the lack of a database of global regulatory approvals for diagnostics and the frequent updating of regulatory approvals, it is recommended that the SRA and/or WHO PQ status of a product is verified through the supplier or the WHO PQ reports to confirm that QA tests are used.[10]

[9] Putting HIV and HCV to the Test 3rd ed., Medecins Sans Frontieres Access Campaign; 2017

[10] WHO diagnostic PQ list.

Quality Assured Viral Load Tests

As illustrated in Exhibit 5, many platforms used to perform HCV VL have broad test menus enabling integrated VL testing with other diseases such as hepatitis B (HBV) and human immunodeficiency virus (HIV). **The ability to leverage these platforms for HCV testing, using HIV diagnostics infrastructures that are present in many LMICs, has provided a critical entry point for public hepatitis programs**. Most of the platforms listed in Exhibit 5 belong to the category of centralized laboratory testing, with GeneXpert being a near point-of-care device. While all of the tests in exhibit 5 have SRA approval, the Abbott Alinity m, m2000 and Cepheid GeneXpert HCV tests are also WHO PQ'd. While not currently in widespread use for HCV VL testing, the future use of dried samples such as dried blood spots or plasma separation cards may enable further decentralized sample collection while leveraging existing centralized diagnostic platforms.

Exhibit 5: Polyvalent Platforms Commonly Utilized in HCV Viral Load Testing

Central Laboratory Based Testing (Non-Exhaustive Test Indications)								
	Abbott Alinity m	**Abbott m2000**	**Roche CAP/CTM**	**Roche 4800**	**Roche 68/8800**	**Hologic Panther**	**Qiagen QiaSymphony**	**Cepheid GeneXpert***
HCV	x	x	x	x	x	x	x	x
HBV	x	x	x	x	x	x	x	x
HIV	x	x	x	x	x	x	x	x
HPV	x	x		x				x
CMV		x					x	
Zika		x				x		
Dengue					x			

*Note: *GeneXpert may be operated as a near point of care platform though is frequently utilized in centralized labs.*

Sources: WHO HCV PQ, Abbott Alinity m, Abbott m2000 tests, Roche CAP/CTM HCV test, Roche CAP/CTM HIV test, Roche CAP/CTM HBV test, Roche 48/68/8800 tests, Hologic tests, Qiagen HCV test, Qiagen HIV test, Qiagen HBV test, Qiagen CMV test, Cepheid Virology (HIV, HBV, HCV) tests, Cepheid Sexual Health (HPV) test.

KEY TAKEAWAY

The use of QA diagnostics is essential to maintaining a high quality of care across the testing cascade. Procurement agents are encouraged to assure the quality of products under consideration.

Pricing Trends

There is no public database on global diagnostics volumes or prices which is routinely updated. The absence of such market data presents significant challenges to pricing and volume transparency and predicting global trends. Previous market intelligence reports have presented volume data and forecasting testing volumes, however these numbers become obsolete over time.[11] This lack of publically available information represents a significant visibility gap in the global diagnostics market.

The pricing structure of diagnostics, both screening and confirmatory tests, is often complex. The final price on an invoice obtained through a traditional agreement includes a number of cost components, which can be challenging for the buyer (MoH, hospital, or other procurement agent) to individually discern.

In addition to the base cost of the test, for example, the final cost may include other components such as:

- Ancillary laboratory reagents, proprietary and non-proprietary consumables
- Instrument rental, service, and maintenance
- Supply chain and distributor margins
- Country specific import taxes and fees

The development of inclusive, supplier-specific global pricing programs with simplified supply chains offers a valuable, streamlined alternative to traditional, non-inclusive diagnostic procurement.

[11] HCV Diagnostics Market Intelligence Report authored by FIND and CHAI; 2017.

Individual contracts, which include specific cost components, may be negotiated on a case-by-case basis, but this can be challenging for smaller programs which often lack significant bargaining advantages. Therefore, the development of inclusive, supplier-specific global pricing programs with simplified supply chains offers a valuable, streamlined alternative to traditional, non-inclusive diagnostic procurement.

Global Pricing Agreements

Several suppliers of HCV VL tests have published global price offers, which combine the base price of the test with one or more additional cost components. Each supplier's pricing model is unique with specific requirements and exclusions. As pricing moves toward increasingly more inclusive agreements, a number of models have been explored. For example, an all-inclusive 'price-per-test' model would cover everything necessary to perform a test in a laboratory, such as instrument placement, reagents and consumables, service and maintenance, and fully-loaded freight and logistics including in-country distribution.

Under some global pricing agreements, the supplier places an instrument in the testing facility at no upfront cost and also covers training, service and maintenance under a single price-per-test. The "placement" of a diagnostics platform is valuable because it reduces set-up and transition costs and also because of the incentive structure in the model; since the supplier's revenue is based solely on testing volumes, the supplier is incentivized to minimize instrument downtime, preempt reagent and consumable stock-outs and ensure that operators are properly trained. The placement of instruments enables flexibility for platform upgrades, or removal at no cost, in order to meet the evolving needs of the user. Some service level agreements may also incorporate key performance indicators (KPIs) that the supplier agrees to meet. These may include indications such as the minimum instrument uptime or the maximum time to respond to a service call or repair an instrument.

Exhibit 6 illustrates the inclusions and specifications of VL global agreements of four common suppliers: Abbott, Cepheid, Hologic, and Roche. These global prices are those the suppliers agree to offer, however this does not preclude countries from potentially negotiating more favorable terms. The tests included in exhibit 6 are those which are included under each supplier's global ceiling prices, however other tests may be offered by the supplier outside of the inclusions of the global program. As can be seen, there are a variety of differences in the additional costs for which the buyer is responsible. The programs all include reagents, proprietary consumables, initial instrument training, calibration, and control standards. The Abbott and Cepheid agreements cover these as ex-works prices. The Roche agreement is Carriage Paid To (CPT) meaning that the supplier is responsible for carriage of the products to the designated location, but not for insuring the goods. The Abbott, Roche and Cepheid agreements may exclude mark-ups for local agent fees, whereas these costs are covered under the Hologic agreement. The Hologic pricing includes instrument placement and the greatest number of cost components of the four agreements, essentially including all costs except non-proprietary consumables, taxes, tariffs, and import duties. While global agreements are shifting toward more inclusive pricing for LMICs, the broadly inclusive terms offered by Hologic's global pricing are noteworthy.

Global donors or procurement agents may also negotiate agreements independent of those presented in exhibit 6 by using other pricing agreements, such as those described in The Global Fund HIV and EID tool, as benchmark.

Exhibit 6: Global Ceiling Agreements for Viral Load Testing

		Global Ceiling Pricing			
		Abbott[a]	**Cepheid[b]**	**Roche[c]**	**Hologic[d]**
Laboratory	Reagents, proprietary consumables and initial instrument training	x	x	x	x
	Calibration and control standards	x	x	x	x
	Invalid results due to instrument errors				x
	Non-proprietary consumables				
Diagnostic Platform	Instrument placement				x[g]
	Instrument training				x
	Service and maintenance				x
Supply Chain	Incoterm[k]	Ex-works	Ex-works	CPT	DAP[l]
	Packaging	x	x	x	x
	Loading from warehouse			x	x
	Pre-carriage			x	x
	Export customs clearance			x	x
	Handling at departure			x	x
	Main transportation			x	x
	Transportation insurance			x	x
	Handling at arrival				x
	Post-carriage				x
	Duties and local taxes				
	Import customs clearance				
	Unloading at destination				
Agreement Specifications	Cost-per-test (US Dollars)	$13.00 - $25.00[e,f]	$14.90	$8.90	$11.28
	Includes distributor and local agent fees	No	No	No	Yes
	Tests included in agreement	HIV EID HCV HBV HPV MTB CT/NG	HIV EID HCV HBV HPV MTB[h]	HIV EID HCV HBV HPV MTB[i]	HIV[j] EID[j] HCV HBV HPV

[a] Abbott global ceiling pricing

[b] Cepheid global pricing

[c] Roche global ceiling pricing

[d] Hologic global ceiling pricing

[e] Abbott price depends on term commitment and test volume

[f] Abbott test volume threshold is based on volume of tests per country

[g] Hologic will place instruments free of charge as long as average tests per instrument exceed 30,000 per year

[h] Cepheid MTB is US$9.98

[i] Roche MTB price depends on sample type. Sputum samples are US$10.67 and sedimented samples are US$8.00

[j] Hologic HIV and EID tests may be less in select countries

[k] Incoterm Table

[l] Hologic will deliver to either the central warehouse or testing site based on customer preference

Agreements in which the instrument is placed free of charge, such as the Hologic Global Access Initiative, may require that the buyer meet annual test volume thresholds. Due to the limited government resources available for hepatitis in many LMICs, public programs may not be large enough to meet test volume thresholds based on HCV testing alone. In these cases, it may be advantageous to pool procurement of HCV tests with those of other disease areas to meet volume thresholds. Achieving this coordinated, cross-disease procurement in a public health program often necessitates strong political will and government budget allocations to facilitate the required centralized purchasing and predictable financial resources.

Despite the availability of global ceiling pricing, the benefits of these inclusive agreements may fail to be fully realized on the ground for a number of reasons. Procurement agents may not understand the specifications of the agreements, or they may simply be unaware of the existence of suppliers' global ceiling prices. In many places, a patchwork of independently operated procurement channels, siloed within specific disease programs is a barrier to pooled procurement and prevents test volumes from attaining numbers necessary to meet thresholds. Additional cost components, which are not included in the agreement, may inadvertently hide the global ceiling price within a greater final cost, which the buyer sees on the invoice such that the buyer may be unsure if they are indeed accessing the global ceiling price.

KEY TAKEAWAY

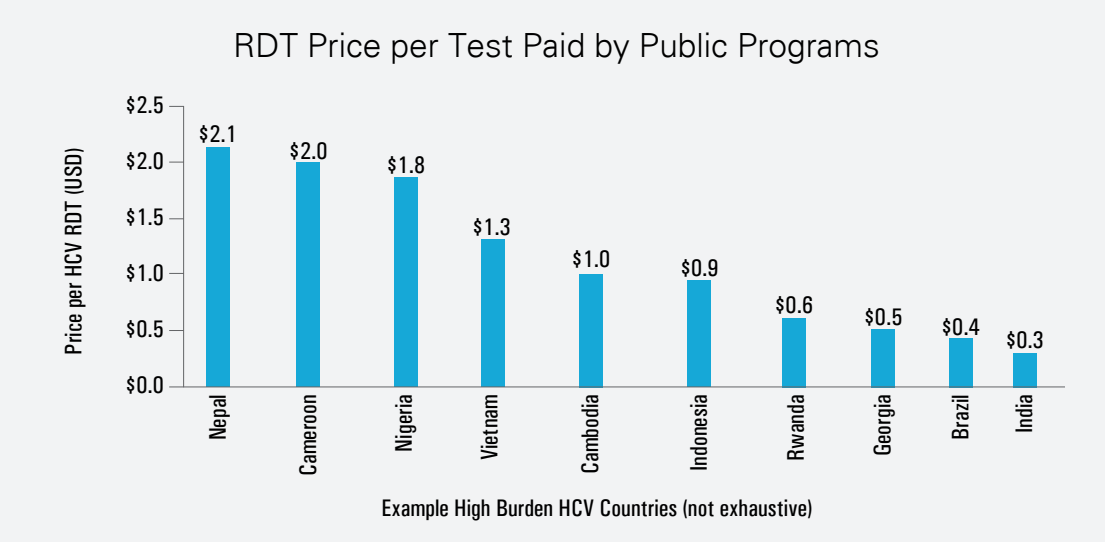
Accessing inclusive pricing agreements enables streamlined procurement and can simplify budgeting and program management. Centralized, pooled procurement of HCV testing with other disease areas enables buyers to meet volume thresholds required by some global pricing agreements.

Prices of Diagnostics Globally

Exhibits 7 and 8 illustrate the RDT and VL prices paid by public programs within a representative sample of HCV high-burden countries. In many countries, there is also significant testing in the private sector. It should therefore be noted that the data presented here are not relevant to the private market and are indicative only of public programs.

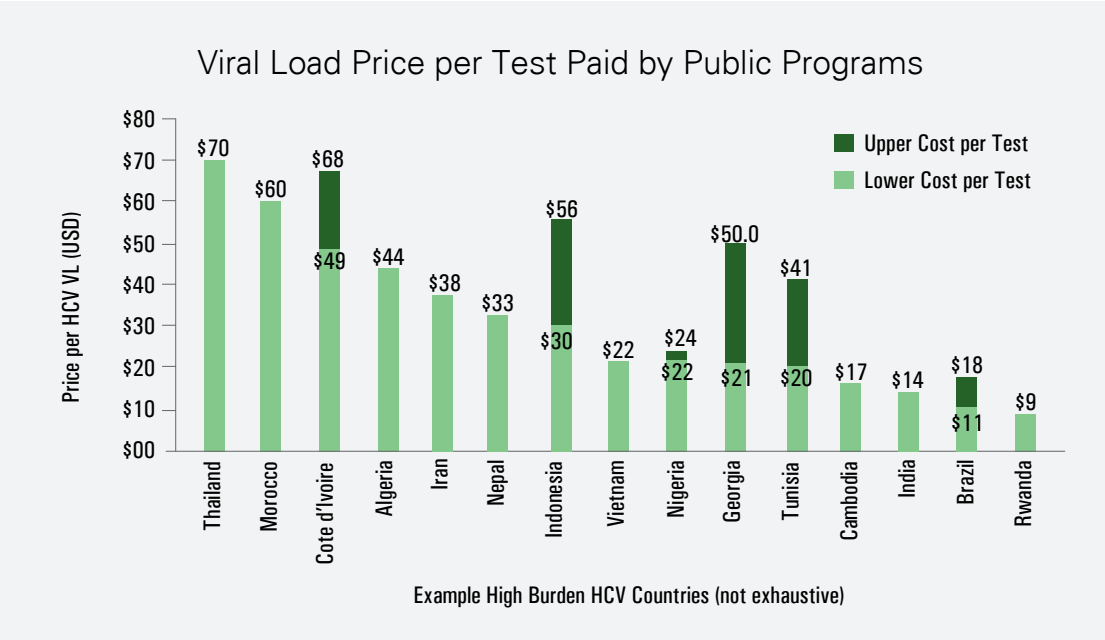
As there are a large number of RDT and VL suppliers, these pricing data represent a range of different suppliers. These data and the countries presented are not exhaustive but rather represent a sample of global prices paid by public programs for HCV diagnostics.

Exhibit 7: RDT Screening Costs to Public Programs



Source: mapCrowd for Nepal, Cameroon, Brazil (mapCrowd accessed on 29th April 2020); CHAI analysis for Nigeria, Vietnam, Cambodia, Indonesia, Rwanda, India; FIND for Georgia; ALCS/ Coalition PLUS for Brazil

Exhibit 8: Viral Load Testing Costs to Public Programs



Note: Where more than one price is paid, the upper and lower prices are indicated by dark and light colored bars respectively.

Source: mapCrowd for Thailand, Morocco, Cote d'Ivoire, Nepal, Iran, Georgia, Tunisia, Brazil (mapCrowd accessed on 29th April 2020); FIND for Cote d'Ivoire, Georgia; CHAI analysis for Indonesia, Vietnam, Nigeria, Cambodia, India, Rwanda; ALCS/ Coalition PLUS for Algeria, Tunisia, Brazil

As illustrated in Exhibits 7 and 8, there may be significant differences in the prices paid for diagnostics both between countries and within a given country. There are numerous potential reasons for the different prices observed globally. One source of the price differences is simply that different products, having different prices, are purchased. When multiple procurement channels exist, individually negotiated contracts will lead to a range of prices within country. Cost components such as import duties, taxes, and tariffs which depend on government regulations vary between countries and may even be waived in some places. These country specific charges, applied when products are imported, result in differences between countries even when procurement occurs through the same global program, unless the charges are included with the global pricing agreement.

Importance of Pricing Transparency

Price visibility on the part of the buyer is essential to guarantee that they are gaining value from inclusive pricing and comprehensively understand the total cost of testing. Without knowledge of the individual cost components, the buyer lacks essential information to engage in contract negotiations, identify opportunities for cost reductions, compare products and services, and accurately assess program budget needs. Without adequate transparency, the buyer may also risk paying duplicative costs. Gaining visibility into the price components is often challenging and it is not uncommon for a buyer to have a limited understanding of the costs that lead to the final price on the invoice. There is no consistent method that can be applied in every situation to obtain visibility into the cost components that lead to the final invoice price. However, through communication with the supplier, government import agencies and the distributor, a complete picture of the costs may be obtained.

[Please refer to Appendix 6 for potential questions and considerations that may be valuable for developing an understanding of the cost components which make up the final price to programs]

The following real-world example in Exhibit 9 illustrates the price components for a GeneXpert HCV test procured via Cepheid's High Burden Developing Country program. While this particular country snapshot relates to Cepheid GeneXpert, price visibility is important across the diagnostics landscape. This particular example is for a specific country at a point in time and does not represent universal cost components for this or other suppliers in all countries, however the addition of similar cost components is broadly generalizable to other suppliers. The addition of margin in this instance is not typical of Cepheid agreements. As can be seen, the final cost of nearly US$22 is significantly greater than the base cost of US$14.90. Despite the modest distributor margin of less than 3 percent,

Exhibit 9: Example of Price Visibility

Cepheid GeneXpert HCV Test Procured via Global Access			
Price Component	**Cost Percentage**	**Incremental** (USD)	**Total** (USD)
Cartridge		**$14.90**	
Freight	8% of Cartridge	$1.19	$16.09
Taxes & Duties	15% of Cartridge	$2.24	$18.33
Distribution	5% of Cartridge	$0.75	$19.07
Service & Support	10% of Final Cost	$2.20	$21.27
Distributor Margin	Flat Rate	$0.37	$21.64
Selling Price			**$21.64**

Confirm that global access price is being accessed

Service is a volume dependent component and should be negotiated each procurement cycle

Import taxes/ duties may be waived by the country in some circumstances

Assure that distributor margin is reasonable

the additional costs constitute nearly a third of the final price of the test. It should additionally be noted that while these costs are described in US dollars, procurement actually occurs in the local currency such that exchange rate fluctuations may have an unpredictable impact on the price paid by the program.

Once a buyer has achieved a complete understanding of the costs similar to the example above, they may be able to identify areas where cost reductions can be made. For example, there may be opportunities to reduce or eliminate government taxes and duties applied to the product. The service and support arrangement may also be flexible with different scenarios yielding benefits as the program scales up. For example, a service and support contract which is charged as a percentage of each test cost may be valuable for a nascent program, but as the program grows, a flat charge independent of testing volume may become more beneficial if the overall cost to the program is lower. Understanding pricing inflection points may be important for the evolution of the program and can only be identified through appropriate price visibility.

The reduced prices for diagnostics that some countries have achieved may serve as benchmarks for other programs to target. Combining multiple procurement channels into a single buyer that is funded by reliable government budget allocations can lower prices and improve price visibility. Pooling diagnostics procurement across diseases boosts testing volumes to better enable the thresholds of some global pricing programs to be met when the volumes of HCV tests alone are low. Negotiating price transparency with suppliers and maintaining good pricing visibility assures that global pricing is accessed, enables informed negotiations, and provides knowledge essential to mitigate excess charges.

KEY TAKEAWAY

Good visibility of the price components for diagnostics is essential for identifying potential cost reductions, enabling informed negotiations with suppliers, and obtaining an accurate appreciation for the budgetary needs of a hepatitis program.

HCV TREATMENT DRUGS

Supplier Landscape

Several generic suppliers have manufactured DAAs and a few have obtained WHO PQ or have been reviewed by the ERP. This section focuses on suppliers of WHO PQ'd/ ERP reviewed DAAs as their products meet international safety standards and have been declared bioequivalent to innovator product.

Quality Assured Generic Suppliers (as of Mar 2020)

SOF and DCV, the most widely used DAAs for HCV treatment in LMICs, have five and three generic suppliers with WHO PQ respectively, indicating a healthy generic supplier landscape for first line treatment. Most other key DAAs or formulations have at least one supplier that has been reviewed by the ERP: SOF/DCV FDC- 1 supplier, SOF/LDV- 2 suppliers, and SOF/VEL- 1 supplier. Exhibit 10 displays the landscape for QA generic suppliers and lists the number of suppliers who have submitted dossiers for WHO PQ and are awaiting prequalification/ ERP outcome.

Exhibit 10: Generic Supplier Quality Status (As of Mar 2020)

	WHO PQ'd	ERP Reviewed
SOF (400 mg)	Cipla, Hetero, Mylan, European Egyptian Pharmaceutical Limited (Pharco)*, Strides	
DCV (60 mg and 30 mg)	Cipla, Hetero, Mylan	Laurus Labs
SOF/DCV (400/60mg)		Mylan
SOF + DCV co-blister (400 + 60mg)	Cipla	
SOF/LDV (400/90 mg)		Strides, Mylan
SOF/VEL (400/100 mg)		Mylan
G/P (300/120 mg)		

*Note: *Pharco's SOF was removed from the Global Fund's list of quality assured products in early 2020 due to non compliance with regulatory requirements. WHO had also conducted an on-site inspection at Pharco's Egypt site in May 2019 where noncompliance with GMP as well as regulatory requirements were identified. The affected batches were recalled by Pharco. A follow-up on-site inspection on implementation of Pharco's corrective and preventative actions by WHO is expected to take place in Q3 2020. For now, Pharco has retained its WHO PQ status.*

Source: The Global Fund List of Antihepatitis Pharmaceutical Products, Jan 2020, Version 19; The WHO list of Finished Pharmaceutical Products (FPPs) that have received WHO PQ as of Mar 2020; The WHO list of FPPs under assessment as of Mar 2020

In-country Supplier Registrations
(as of Q4 2019 – Q1 2020)

Drug suppliers are required to register their products in-country before commercializing them. Product availability can be delayed in countries where the drug registration process is lengthy and lasting over six months depending on the country requirements. This can limit options available for procurement, and reduce or delay market competition among suppliers in-country.

Countries that have a larger number of suppliers registered for DAAs can access more product options, ensure supply security in-country, and increase competition among suppliers in order to potentially access products at lower prices. A larger supplier network also allows for more successful tender processes. For example, Myanmar has over 10 generic suppliers registered in-country for SOF and three generic suppliers registered for DCV. Registered suppliers could be WHO PQ'd/ ERP reviewed, or could be meeting only local quality standards. In the latest tender in 2019, Myanmar was able to secure a price of US$93 per patient course for a 12-week treatment with SOF and DCV. This price is lower than the price that several other high-burden countries are paying for HCV treatment. Similarly, India has 10 or more suppliers registered for both SOF and DCV and the national tender was able to secure a price of US$39 per patient course for a 12-week treatment with SOF and DCV in 2019. The public programs of both India and Myanmar procure locally approved products, but not WHO PQ'd/ERP reviewed products. While registering multiple suppliers may help to lower in-country prices, as observed in India and Myanmar, situations can arise where structural barriers in country continue to keep prices high. For example, the price for SOF in Vietnam is US$750 for 12 weeks of treatment per patient despite 13 suppliers being registered in-country.

[Please refer to Appendix 4 for in-country supplier registration status of key drugs]

Suppliers and countries can consider using the WHO's Collaborative Registration Procedure (CRP) for accelerating registration of DAAs in-country. The CRP aims to leverage the work of the WHO Prequalification of Medicines Program during in-country registration of WHO-PQ'd medicines. It enables national medicines regulatory authorities to utilize outcomes of the WHO PQ evaluations and inspections. This can help shorten time for registration of products in-country by reducing duplication of work. Countries could save time and resources if they leverage CRP and do not require a full assessment of the PQ'd product or manufacturing site inspections. The agreed target for registration in country via the CRP is 90 days once filed in country.

KEY TAKEAWAY

Countries can seek opportunities to accelerate registration/ time limited import approval of WHO prequalified/ERP reviewed products to ensure product availability, supply security, and access to affordable prices by fostering competition.

Volume Trends

Understanding accurate volume trends for DAA uptake in LMICs has been challenging due to poor availability of historical data on drug procurement and lack of a central procurement mechanism widely used by LMICs. The analysis in this section broadly leverages the India Import Export Database to provide some indication on historical volume trends; however, the database has certain limitations. First, it only captures exports from India and does not represent information on locally manufactured and procured drugs in other countries such as in Vietnam, Pakistan and Egypt. Second, it does not account for drugs exported from other countries that have generic DAA suppliers such as Pharco in Egypt. Third, the data does not account for sales or donations made by innovator suppliers such as Gilead and Bristol Myers Squibb (BMS) in LMICs. These three limitations may lead to underestimation of volumes of drugs procured by LMICs in Exhibit 11. Further, predicting future volume trends has been challenging due to a non-linear historical procurement pattern by countries and lack of clarity on future procurement budgets, leaving the HCV community with little scope to predict the future demand for DAAs.

Insights based on the volume trends in Exhibit 11 are as follows.

The generic SOF and DCV procurements from Indian generic suppliers have increased over the last few years. However, the market for DAA's has been variable and unpredictable. Some of the reasons for the variability are as follows:

In the past, the increase in uptake was driven by a few countries that had scaled-up HCV treatment. Egypt, Pakistan, and India accounted for 84 percent of the SOF procured from Indian suppliers in 2018. However, Egypt and Pakistan reduced their order volumes by ~60 percent in 2019. These countries have treated the majority of their diagnosed patients and are now focusing on case finding activities. As countries approach elimination by treating most of their patients, the demand for DAAs in those specific countries might peak and then decline.

While Pakistan, Egypt, and India have made more progress toward elimination than most other LMICs, some of the other high-burden LMICs such as Rwanda, Ukraine, and Uzbekistan are now scaling up procurement of generic DAAs. The overall demand for DAAs might increase in the coming years if LMICs continue to scale up treatment. However, due to lack of clarity on country budget allocations and procurement plans, it is difficult to estimate an accurate future demand for DAAs.

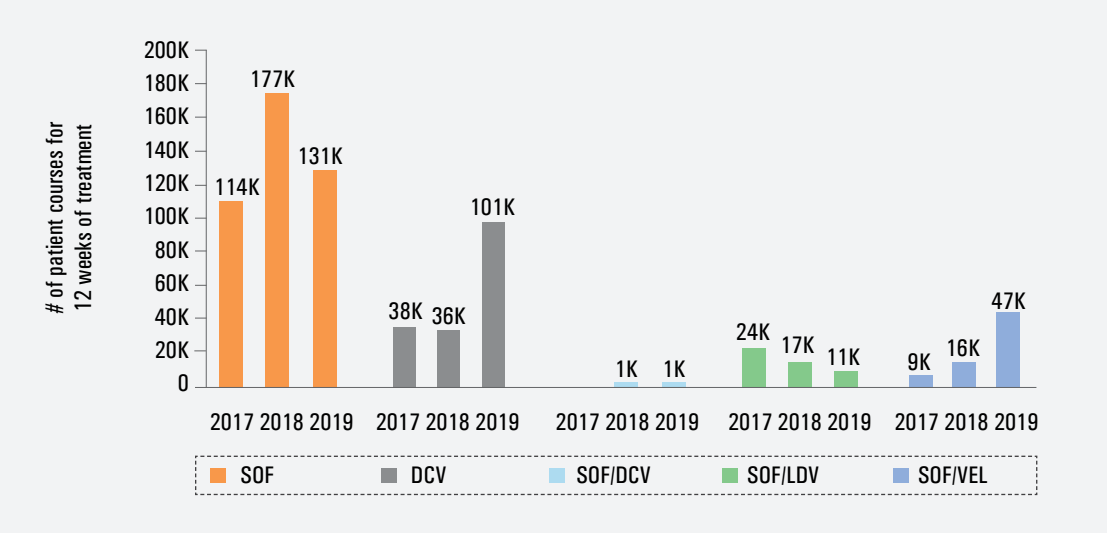
Among other LMICs, procurement of DAAs has been non-linear in the past, implying that countries do not tend to procure at regular intervals. For example, Indonesia procured 3,200 patient courses of SOF for 12 weeks of treatment across Q2, Q3, and Q4 in 2018 from generic suppliers in India, and then directly procured 4,200 patient courses of SOF for 12 weeks of treatment in Q4 of 2019. **Procurement planning and transparency on procurement timelines from countries can help suppliers obtain visibility on in-country requirements and plan production capacity accordingly, potentially making products available with shorter lead-times**.

Some countries might be diversifying their procurement sources based on domestic availability of drugs and donations. For example, the significant

volume difference between SOF and DCV procured from Indian suppliers in 2017 and 2018 could be a result of Pakistan and Egypt pairing locally manufactured DCV with SOF manufactured by Indian suppliers.

Market introductions of generic SOF/VEL and SOF/DCV FDC offer countries two new pan-genotypic regimen options or formulations for procurement. Decline in exports of SOF/LDV (non-pan-genotypic regimen), increase in exports for SOF/VEL (pan-genotypic regimen), and uptake of SOF/DCV FDC and SOF + DCV (pan-genotypic regimen) indicate, not surprisingly, a preference for pan-genotypic regimens over non-pan-genotypic regimens.

Exhibit 11: 2017–2019 India Generic DAA Export Volumes to Lmics and India Volumes



Note: SOF and DCV refer to singles, whereas SOF/DCV, SOF/LDV and SOF/VEL refer to FDCs;

Punjab patients initiated on treatment used as proxy to calculate number of patient courses procured in India; Number of patients initiated on treatment in Punjab represent ~80% of patients initiated on treatment in India; Only orders >50 bottles in the India Import Export data included in analysis; Each bottle has 28 pills.

Source: India Import Export Data; CHAI Analysis.

KEY TAKEAWAY

- India, Egypt, Pakistan, Rwanda are examples of countries that have committed to scaling up their HCV programs. To accelerate progress towards HCV elimination, countries will need to intensify case finding efforts. Countries that prioritized patients who were previously diagnosed and awaiting care for HCV treatment will need to focus on active case finding.
- Several other LMICs are expanding their HCV treatment programs but slow treatment uptake is a risk to achieving WHO elimination goals by 2030.
- Limited data on in-country DAA procurement and procurement budgets has restricted capability to predict future market trends for DAAs. Increased procurement planning and transparency on in-country procurement plans can help suppliers identify future demand for DAAs and plan production accordingly, potentially making products available with a shorter lead-time.

Pricing Trends

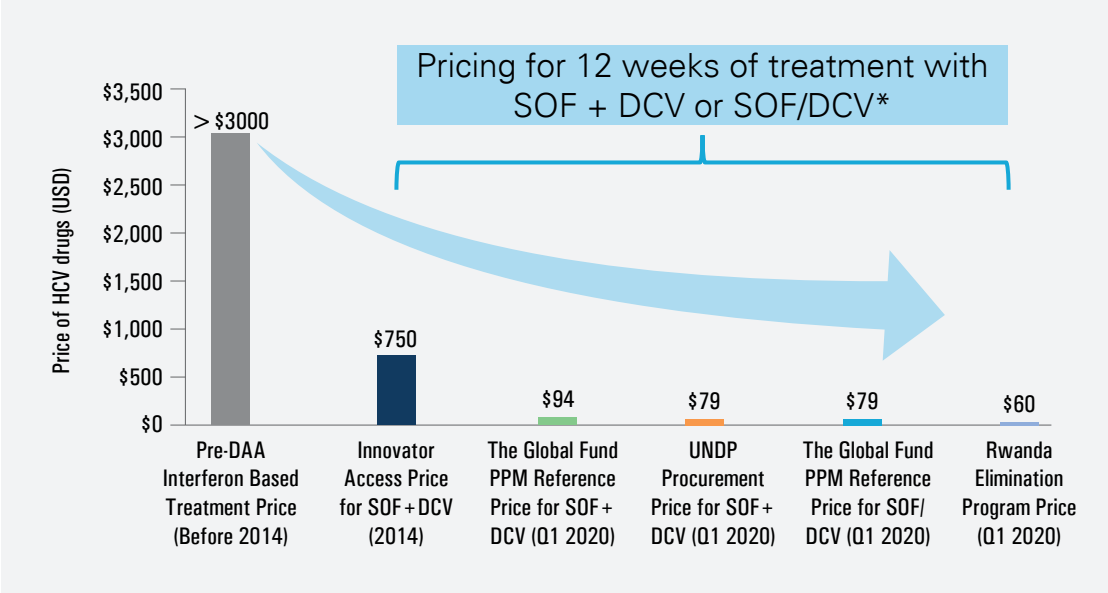
The price of HCV treatment has fallen significantly over the past five years with the introduction of more effective treatment and expansion of the generic landscape for DAAs. Exhibit 12 illustrates that before 2014, there were no DAAs in the market and price for interferon-based therapy was over US$3,000 per patient course. In 2014, with the introduction of DAAs, the price per patient course offered by the innovators was over US$750. More recently, the price for WHO PQ'd generic SOF and DCV has come down to US$60 per patient course for 12 weeks in Rwanda, making this price the new global benchmark price for WHO PQ'd HCV treatment. While some countries such as India, Pakistan, and Egypt are paying lower than US$60 per patient course, they are procuring locally approved products, which can be manufactured at a lower cost than WHO PQ'd products.

Exhibit 13 summarizes the weighted average price for a 12-week DAA treatment course in LMICs. Prices are shown in 'Freight On Board' (FOB) terms. These are prices at which generic suppliers export drugs from India. They do not include shipping, customs, storage, and distributor-associated costs. Usually there are in-country costs added to the FOB price, resulting in a higher final price to the buyer (price mark-ups addressed in detail in subsection on 'In-country Price Mark-ups').

The trend in Exhibit 13 indicates that FOB prices for DAAs exported from India have reduced significantly

The Rwanda HCV Elimination Program was launched in December 2018. As part of the program, the Rwanda Ministry of Health committed to eliminate HCV by treating 112,000 patients over a period of five years (2019-2024). The strong political will to scale-up the public program and eliminate HCV helped Rwanda obtain a price of $60 per 12-week patient course with WHO PQ SOF + DCV. This price was obtained without a volume guarantee. Rwanda now plans to accelerate the timeline for HCV elimination to 2021.

Exhibit 12: Price Evolution of HCV Drugs (USD)



*Note: *SOF + DCV refers to a combination of SOF and DCV singles; SOF/DCV refers to FDC.*

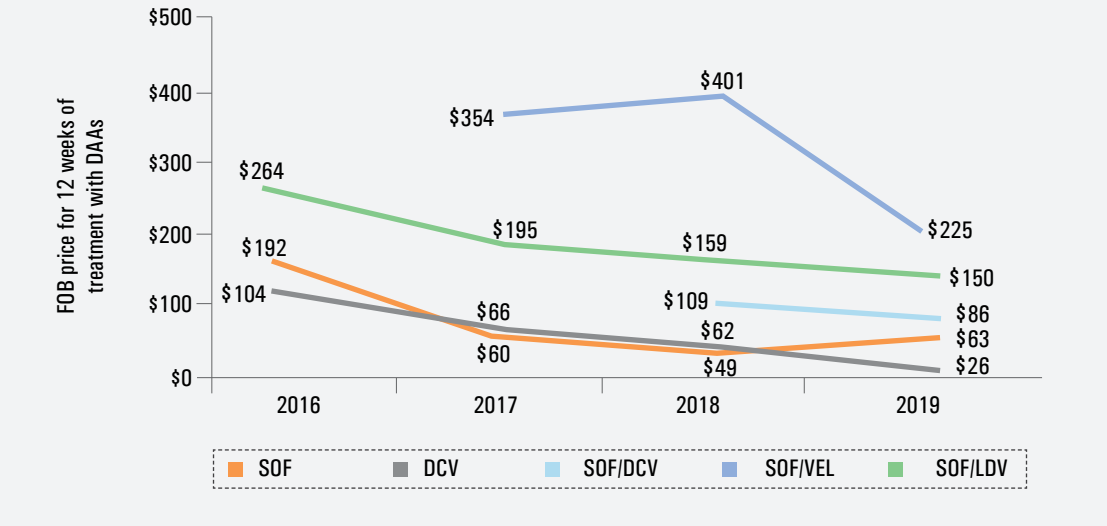
Source: CHAI Analysis; The Global Fund Pool Procurement Reference Pricing as of Jan 2020; UNDP procurement support team as of Apr 2020.

from 2016 to 2020. This trend can be attributed to an increase in the number of generic drug suppliers manufacturing DAAs and an increase in volumes as some countries scale-up.

As of 2019, SOF/DCV FDC was exported at the lowest weighted average FOB price (US$86 per patient course for 12 weeks), followed by a combination of individual SOF and DCV (US$89 per patient course for 12 weeks).

FOB price for SOF/VEL declined in 2019 as volumes demanded by LMICs increased. Countries including India, Myanmar, and Pakistan procured SOF/VEL in large quantities from Indian suppliers in 2019.

Exhibit 13: Weighted Average FOB Price* (USD) for 12 Weeks of Treatment with DAAs in LMICs



*Note: ^SOF and DCV refer to singles, whereas SOF/DCV, SOF/VEL and SOF/LDV refer to FDCs; *Pricing reflects 'Freight on Board' price, which does not include shipping, customs and distributor-associated costs. Usually there are in-country costs added to the FOB price which result in a higher final price to the buyer; The price is weighted average of volumes of all orders >50 bottles and their respective prices per bottle; Only orders above 50 bottles considered; Each bottle has 28 pills; Prices are for both WHO PQ'd/ ERP reviewed and locally approved products.*

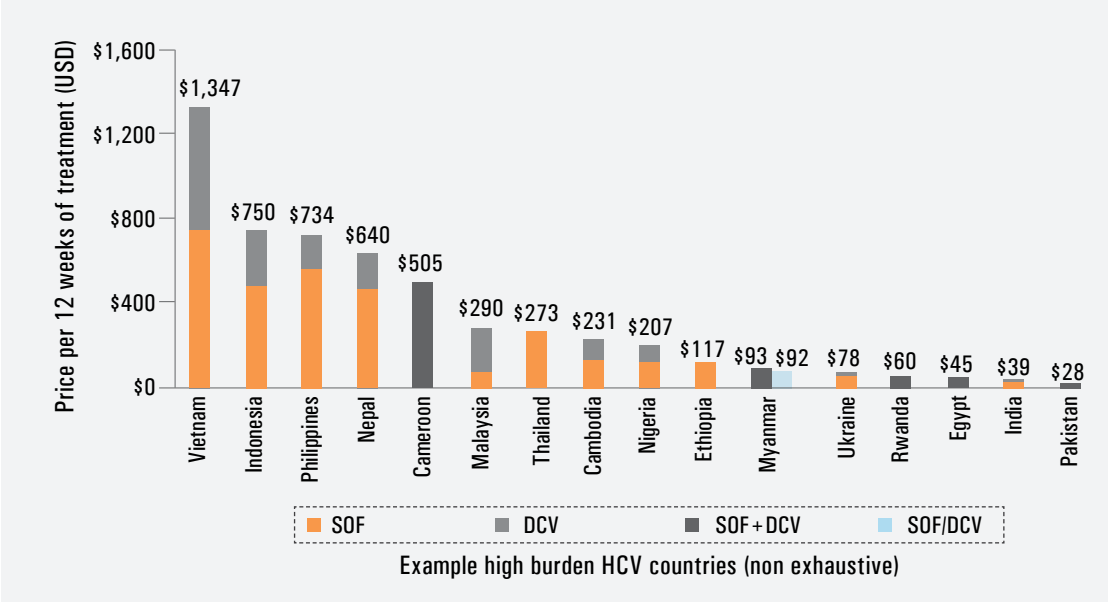
Source: India Import Export Data.

SOF/LDV and SOF/VEL are comparatively expensive regimens based on FOB prices, however, the in-country price trend may differ from one country to another. For example, the in-country price of both SOF/VEL and SOF/LDV is cheaper than the price of SOF + DCV in Vietnam. This is due to the limited number of DCV products available in-country, combined with a large number of locally approved SOF/LDV suppliers ensuring a competitive market for this product. Three DCV products have been registered in Vietnam since Q4 2019, which may lead to a decline in DCV price in the future. In the case of SOF/VEL, Gilead registered its product in Vietnam in 2019 and offered the product at a lower price than that of SOF + DCV.

While the global benchmarks for DAA prices have declined, there is significant variability in prices across high-burden countries. Exhibits 14, 15, and 16 show that while some countries are accessing DAAs at less than US$40 per patient course for 12 weeks, some are paying more than US$700 per patient course for 12 weeks. There is no standardized global price that countries are accessing yet. In-country procurement mostly occurs by either the private sector, or the public sector through tenders or country specific negotiations with suppliers.

Egypt, India, and Pakistan have secured very low prices for DAAs across regimens as they are scaling-up public programs rapidly and moving towards HCV elimination. However, these countries are using locally approved products (that are not WHO PQ'd/ERP reviewed), which tend to be less expensive. While the prices of non-WHO PQ'd products are lower, they could indicate lower limits for pricing possible on commoditized WHO PQ'd products (i.e. products which have been manufactured at a large scale for more than three years).

Exhibit 14: In-country Price for 12 Weeks of Treatment with SOF and DCV*



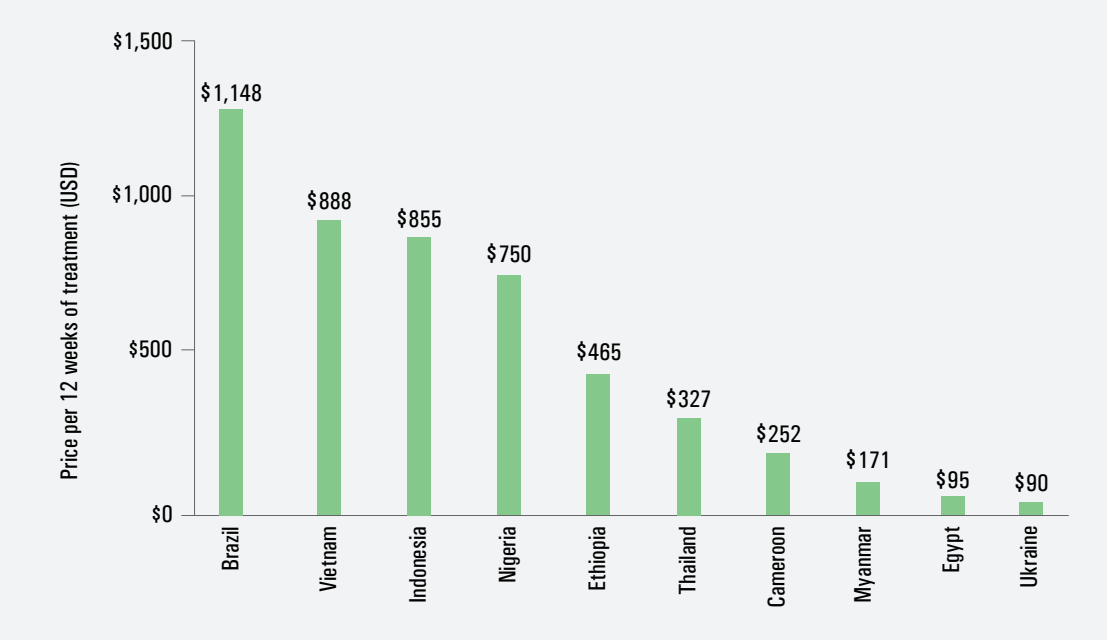
*Note: *SOF and DCV refer to singles, SOF + DCV refers to a combination of SOF and DCV singles, SOF/DCV refers to FDC;*

The prices mentioned are public sector prices paid by govt. in country if available, or lowest identified private sector prices if public sector price not available;

Prices shown can be for originator or generic product; Amongst generic products, prices can be for WHO PQ'd/ ERP reviewed or locally quality assured products; Price data for DCV not available for Ethiopia and Thailand; Price breakdown between SOF and DCV not available for Cameroon, Myanmar, Rwanda and Pakistan; DCV price for Vietnam as of Q1 2019 as DCV was unavailable in-country from Q2 2019 - Q1 2020; Prices as of 2018 for Nepal, and as of 2019 for all other countries.

Source: CHAI analysis for India, Nigeria, Indonesia, Vietnam, Rwanda, Cambodia, Myanmar, Ethiopia; Coalition PLUS for Malaysia; Treat ASIA/amfAR Aug 2018 and Sep 2019 updates for Ukraine, Thailand and Nepal; World Hepatitis Alliance and members for Egypt, Philippines and Cameroon; Aga Khan University for Pakistan.

Exhibit 15: In-country Price for 12 Weeks of Treatment with SOF/LDV*

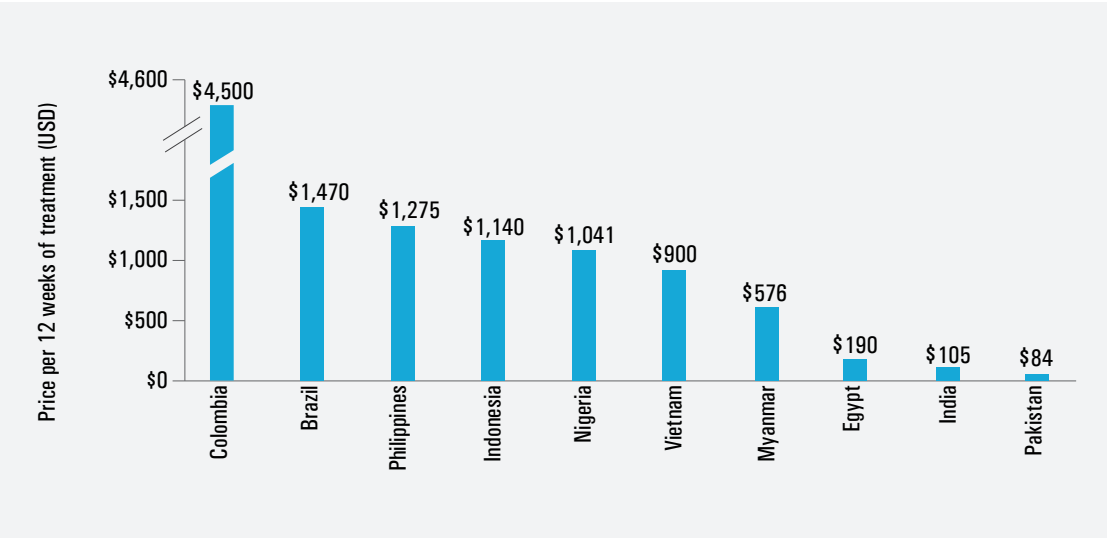


*Note: *SOF/LDV refers to FDC; SOF/LDV is not a pan-genotypic DAA regimen and is not recommended by WHO for use in adults. However, it remains the only WHO-recommended all-DAA regimen for adolescents (12-17 years).*

The prices are public sector prices paid by govt. if available, or lowest identified private sector prices if public sector in-country price not available; Prices shown can be for originator or generic product; Amongst generic products, prices can be for WHO PQ'd/ ERP reviewed or locally quality assured products; Prices as of 2019.

Source: CHAI analysis for Nigeria, Indonesia, Vietnam, Myanmar, Ethiopia; Coalition PLUS for Brazil; Treat ASIA/amfAR Aug 2019 updates for Ukraine and Thailand; mapCrowd for Egypt (mapCrowd accessed on 29th April 2020); World Hepatitis Alliance member for Cameroon.

Exhibit 16: In-country Price for 12 Weeks of Treatment with SOF/VEL*



*Note: *SOF/VEL refers to FDC;*

The prices are public sector prices paid by govt. to the supplier if available, or lowest identified private sector prices if public sector in-country prices not available; Prices shown can be for originator or generic product; Amongst generic products, prices can be for WHO PQ'd/ ERP reviewed or locally quality assured products; Prices as of 2019.

Source: CHAI Analysis for India, Nigeria, Indonesia, Vietnam, Myanmar; Coalition PLUS for Colombia and Brazil; World Health Alliance member for Philippines; mapCrowd for Egypt (mapCrowd accessed on 29th April 2020); Aga Khan University for Pakistan.

Patients receive treatment for HCV in Vietnam

Patients accessing treatment through the public sector program in India can access SOF + DCV and SOF/VEL free of charge. Similarly, patients in Rwanda, Myanmar, and Indonesia can access SOF + DCV free of charge through the public sector program. Before India's launch of its National Program in July 2018 in India, SOF/LDV was available free of charge to patients in Punjab and Haryana. The National Program now recommends the use of SOF with DCV, and SOF/VEL, which are available free of charge to public sector patients. As the national program no longer recommends the use of SOF/LDV, patients would now have to pay out-of-pocket to access this drug. Similarly, patients pay out-of-pocket for SOF/LDV and SOF/VEL in Myanmar, and Indonesia. In Nigeria, while the drugs are procured through the MoH to facilitate pooled procurements and volume-based pricing benefits, patients pay out-of-pocket for drugs at public sector hospitals with a minimal price mark-up above the MoH procurement price to cover basic operational costs. In Cambodia, patients co-infected with HIV and HCV on Antiretroviral Therapy (ART) could access SOF and DCV free of charge in the public sector, but paid out-of-pocket for other regimens.

However, across countries where drugs are procured by the public program and provided free of charge to patients, procurement is limited by available budget. Hence, there are limited volumes of drugs available free of charge for treatment of public sector patients, which might lead to public sector patients having to wait to be able to obtain treatment for free.

Given the lack of funding for HCV treatment, some high-burden countries have identified alternative ways to reduce price of treatment to patients. For example:

In Vietnam, regimens are available in public hospitals where patients can pay out-of-pocket for treatment. The Vietnam government formally announced in 2018 that as of 1st January 2019, 50 percent of HCV drug costs will be covered by the public health insurance scheme in National and Provincial health facilities — a significant step toward sustainable financing. This effort aims to reduce the financial burden to patients, who were facing high out-of-pocket expenses for drugs and diagnostics.

Myanmar has initiated a public-private partnership model in three public healthcare facilities across Yangon and Mandalay so that patients diagnosed in both the public and private sectors that are ineligible for free care through the public program, but willing and able to pay out of pocket, have access to WHO PQ'd/ ERP reviewed drugs and lab services at reduced costs.

Some other high-burden countries are working toward expanding their HCV programs to increase access to treatment. For example:

Indonesia expanded its national hepatitis program to seven new provinces in 2018 and one new province in 2019. This led to hepatitis treatment being available in 15 out of 34 provinces in Indonesia. In Morocco, the public sector has not yet begun treatment of HCV with DAAs, but is working toward it.

A significant step forward has been made in Nigeria, building off CHAI's efforts in Nasarawa. In February 2020, the Governor of Nasarawa State announced the government's commitment to scale-up HCV elimination efforts, with the goal to treat 124,000 HCV patients and eliminate HCV by 2024. This

State Governor's HCV elimination dialogue, Nasarawa, Nigeria *© Nasarawa State Government*

creates a platform for possible collaborations and opportunities for market-shaping discussions that can further accelerate the uptake of HCV diagnostics and curative treatments.

High-burden middle-income countries such as Brazil and Colombia are still paying high prices for originator DAAs as they are not included in BMS, Gilead, and AbbVie's licensing agreements for DAAs.

Brazil is procuring SOF/LDV and SOF/VEL from Gilead, and the products are available in the public sector.

Colombia has two main insurance schemes: the contributory plan and the subsidized plan. The contributory regime is administered federally and applies primarily to a cadre of public employees and self-employed workers with contributory capacity. The subsidized (non-contributory) scheme is for informal workers and low-income self-employed workers. Procurement via the PAHO Strategic Fund for Epclusa (originator SOF/VEL at >US$4,000 for 12 weeks) has been limited to procurement by the contributory plan. However, negotiations are in process to allow the subsidized scheme to be linked with the procurement of DAAs via orders to the PAHO Strategic Fund.

Georgia is on track to achieve elimination by 2025 and it is estimated that ~50 percent of Georgia's population of ~4 million people has been screened and ~44,500 have been cured, as of Mar 2020. Georgia's progress so far has been helped by a drug donation from Gilead, strong political backing and information systems, availability of HCV commodities, engagement with civil society, and advocacy.

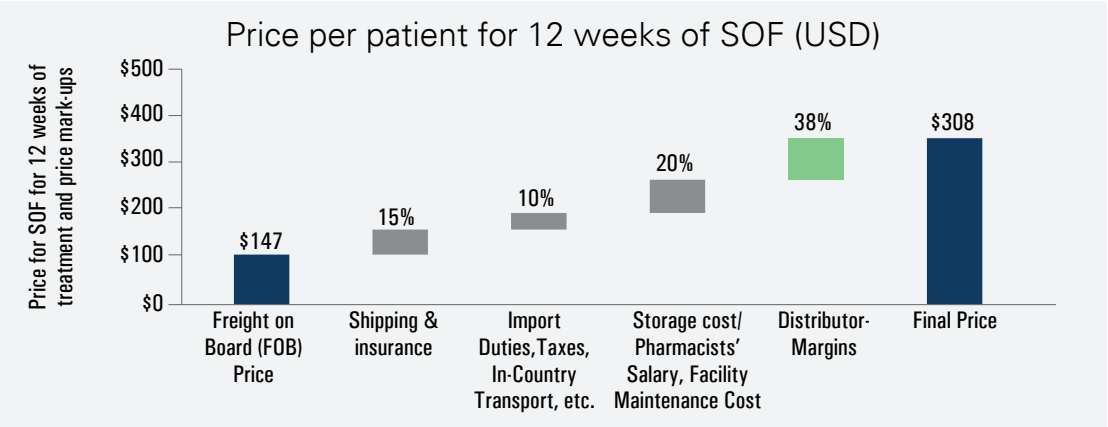
KEY TAKEAWAY

- Global benchmark prices for drugs have declined significantly.
- However, many countries continue to pay exorbitant prices. LMICs can aim to achieve a price of less than US$100 per patient course for 12 weeks of treatment with WHO PQ'd SOF and DCV.
- Countries can also aim for $60 per patient course for 12 weeks of treatment with WHO PQ'd SOF and DCV if there is strong public commitment by government to HCV elimination over a defined period of time and procurement volumes are large, as observed in Rwanda.

In-country Price Mark-ups

Prices remain high for HCV medications in some countries despite a decline in FOB prices offered by generic suppliers. This trend can be attributed to in-country price mark-ups. In-country mark-ups may include shipping and insurance, import duties and in-country taxes, storage, facility maintenance and transportation costs, pharmacists' salaries, distributor margins, etc., as illustrated in Exhibit 17.

Exhibit 17: In-country Fixed and Variable Costs Included in DAA Pricing (Illustrative; Non-exhaustive List of Sources of Price Mark-up)

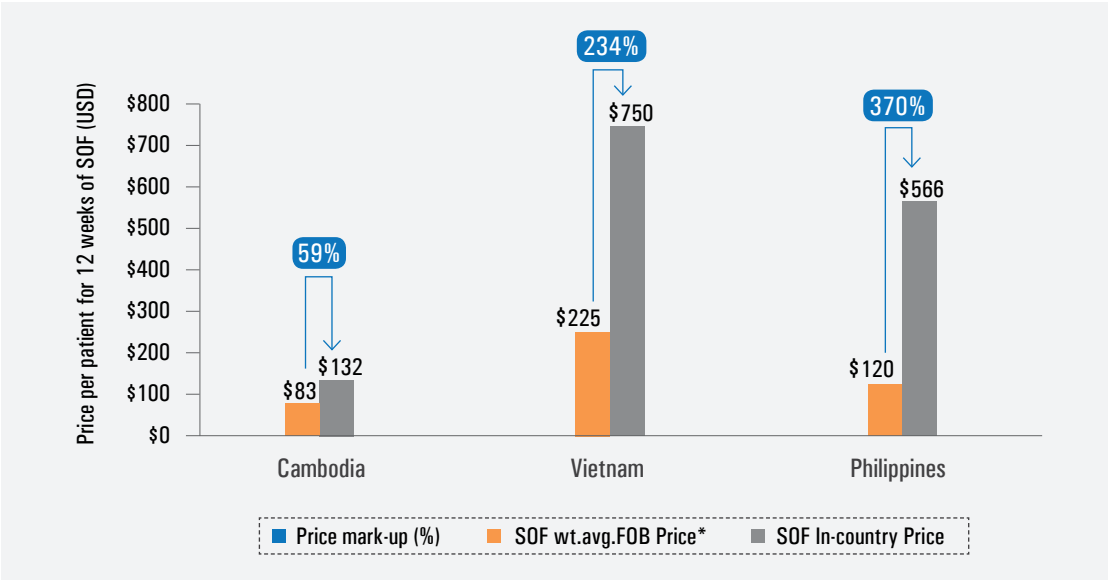


Note: 'Freight on Board' (FOB) is the price at which the supplier exports the drug from the country. This price does not include price mark-ups.

Evaluating what the breakdown of the various price mark-ups are (such as supply chain related costs and profit margins) is important. This could provide countries with the opportunity to work toward optimizing price-to-patient.

Exhibits 18 and 19 demonstrate an indicative range of price mark-ups across countries, with some countries paying small mark-ups while others paying large mark-ups.

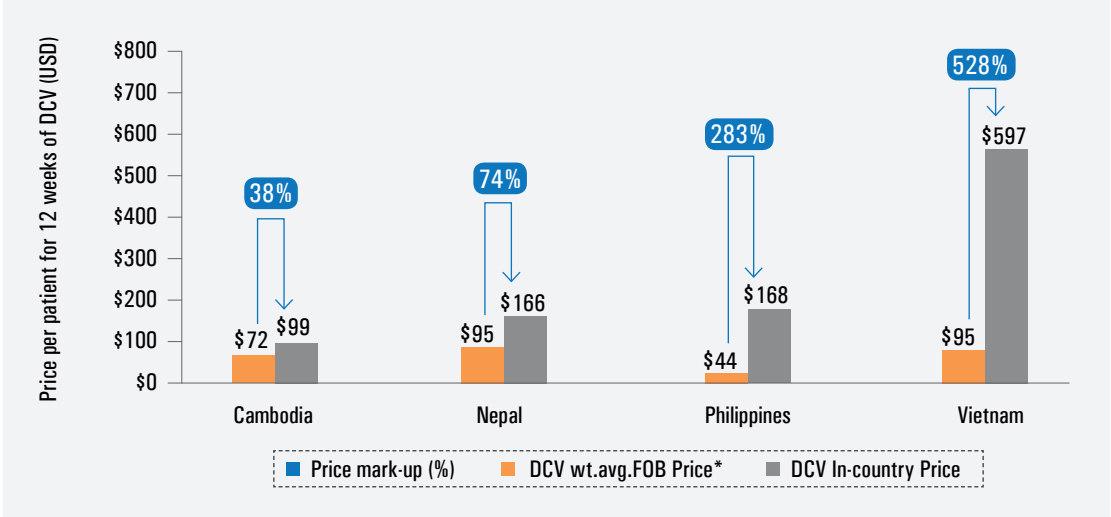
Exhibit 18: In-country Price Mark-ups on SOF (Indicative)



*Note: *'Freight on Board' (FOB) prices are prices at which the supplier exports the drug from the country. These prices do not include shipping, customs, storage and distributor-associated costs; The SOF FOB price is the weighted average of volumes of orders >50 bottles and their respective price per bottle; In-country price mark-ups are indicative and only directional as weighted average FOB price of multiple suppliers is compared with in-country price offered by a single supplier.*

Source: India Import Export Data for FOB price; CHAI analysis for Indonesia, Cambodia and Vietnam in-country prices; World Hepatitis Alliance member for Philippines in-country price; CHAI analysis for mark-up percentages.

Exhibit 19: In-country Price Mark-ups on DCV (Indicative)



*Note: *'Freight on Board' (FOB) prices, which are the prices at which the supplier exports the drug from the country. These prices do not include shipping, customs, storage and distributor-associated costs; The DCV FOB price is the weighted average of volumes of all orders >50 bottles and their respective price per bottle; In-country price mark-ups are indicative and only directional as weighted average FOB price of multiple suppliers is compared with in-country price offered by a single supplier.*

Source: India Import Export Data for FOB price; CHAI analysis for Cambodia, Indonesia and Vietnam in-country price; Treat ASIA/amfAR Aug 2018 for Nepal in-country price; World Hepatitis Alliance member for Philippines in-country price; CHAI analysis for mark-up percentages.

KEY TAKEAWAY

Countries observing high price mark-ups can reduce prices by identifying different contributing factors and limiting them where possible.

International Procurement Mechanisms

International and regional organizations such as GFATM, UNDP, and PAHO have implemented central mechanisms through which they pool procurement and negotiate lower prices with suppliers. Countries can consider these mechanisms for product procurement. Countries can also use the prices offered by these mechanisms as benchmarks for local tenders, or for negotiating price deals with suppliers.

The Global Fund Pooled Procurement Mechanism (PPM): GFATM leverages its position as one of the largest buyers of antiretroviral (ARV) drugs and other related HIV health products in the global health market to establish framework agreements and negotiate reference prices for several key, yet often low-volume, essential medicines recommended by WHO. GFATM leverages the PPM to aggregate order volumes on behalf of participating grant implementers to negotiate prices and delivery conditions with suppliers.

The current prices negotiated by GFATM for 12 weeks of HCV treatment are ~US$94 for individual SOF + DCV, ~US$79 for SOF/DCV FDC, and US$165 for SOF/LDV. GFATM procures DAAs from WHO PQ'd/ERP reviewed suppliers only.

Learn more about The Global Fund Pooled Procurement Mechanism here.

Learn more about The Global Fund's terms for HCV drugs being open to other buyers to PPM here.

The UNDP Health Procurement Mechanism: The UNDP Health Procurement Mechanism supports Ministries of Health with procurement services for DAAs. UNDP also provides advice on intellectual property, regulatory aspects, and national supply chain strengthening. A hundred and five countries (refer to Appendix 3.3 for names of countries) can access the UNDP procurement mechanism by signing a Financing Agreement with UNDP Country Office (CO) and transferring funds to the CO. UNDP prioritizes quality-assured health products.

The current prices negotiated by UNDP for 12 weeks of HCV treatment are US$79 for SOF + DCV, US$90 for SOF/LDV, and US$270 for SOF/VEL. UNDP procures SOF + DCV and SOF/LDV from WHO PQ/ERP reviewed suppliers only. When UNDP negotiated prices, there were no QA suppliers for SOF/VEL; hence, UNDP conducted in-house assessment of manufacturing sites and product dossiers before procuring SOF/VEL from supplier(s).

In 2018-2019, UNDP procured DAAs for ~20,000 patients in Kazakhstan (all patients on SOF and DCV) and ~3,600 patients in Ukraine (2,690 patients on SOF/LDV, 950 on SOF and DCV). In 2019, UNDP procured SOF and DCV for ~400 patients in Azerbaijan. For 2020-2021, Turkmenistan plans to outsource procurement for 500 patients on SOF/VEL, and 500 patients on SOF and DCV.

PAHO Strategic Fund: PAHO's Strategic Fund offers technical support in procurement planning and supply management of DAAs. It negotiates with different international suppliers to obtain lower product prices in the Americas. The Member States (list available in Appendix 5) can purchase DAAs through the Strategic Fund.

The most recent prices negotiated by the PAHO Strategic Fund for 12 weeks of HCV treatment are ~US$129 for SOF and DCV, and US$4,050 for SOF/VEL or SOF/LDV. All products offered through the Fund meet PAHO/WHO quality standards.

However, several member countries are unable to access the Strategic Fund negotiated prices because they have not been included in BMS/Gilead's licenses. As a result, these countries may end up paying more than the price negotiated by the Strategic Fund.

Learn more about the PAHO Strategic Fund here.

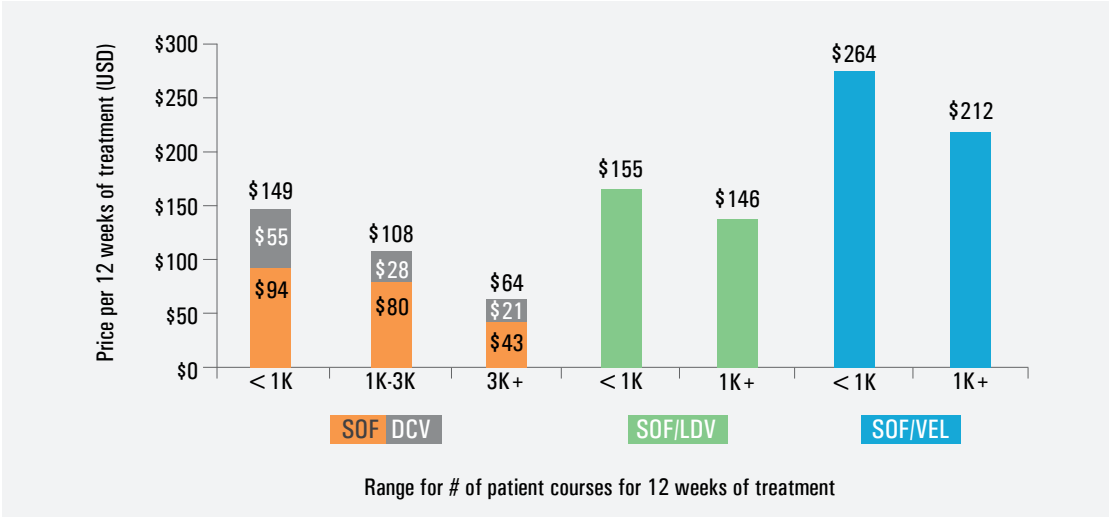
KEY TAKEAWAY

Countries can explore global procurement mechanisms to procure HCV treatment at a more affordable price. Countries can also use the prices offered by these mechanisms as benchmarks for local tenders, or for negotiating price deals with suppliers.

Volume Based Pricing

Programs that have aggressively scaled-up treatment volumes have usually benefited from significant price breaks, as shown in Exhibit 20. For orders in the range of over 3,000 patient courses[12] of SOF and DCV, Egypt and Pakistan have been able to receive very competitive FOB prices, of up to 125% reduction over orders in the range of 1,000-3,000 patient courses[12]. Rwanda too has procured over 3,000 patient courses[12] and has obtained a competitive price for DCV. However, DCV exported to Rwanda is more expensive than DCV exported to Pakistan despite higher order volumes in Rwanda. This could be driven by the fact that Rwanda is procuring WHO PQ'd products while Pakistan might be procuring locally approved products without WHO PQ. Non WHO PQ'd products can be cheaper than WHO PQ'd products

Exhibit 20: 2019 Volume Based Pricing for DAAs (USD)



Note: Only orders going to LMICs and above 50 bottles considered; Each bottle has 28 pills; Two orders of SOF going to Indonesia in the range of 1K-3K patient courses each excluded as they were outliers

Source: India Import Export Data

[12] Each patient course for 12 weeks.

Exhibit 21: 2019 FOB Prices for Orders in the Range of >3K Patient Courses

	SOF		DCV	
	# patient courses	FOB price for 12 weeks of treatment (USD)	# patient courses	FOB price for 12 weeks of treatment (USD)
Egypt	~39.7K	~US$39		
Pakistan	~8.7K	~US$32	~17.1K	~US$10

Source: India Import Export Data

Countries without the resources to procure high volumes can still optimize order sizes through quantification and procurement planning exercises to ensure they receive the lowest volume-based pricing.

KEY TAKEAWAY

Country programs can benefit from lower pricing by planning procurement and ordering DAAs in optimal quantities.

Looking Forward

While several countries including India, Pakistan, Egypt, and Rwanda have scaled-up their programs and are consequently on the path to elimination, global progress toward WHO 2030 HCV elimination goals is slow. The increasing availability of cost effective, QA diagnostics and treatment options, in parallel with the simplified WHO guidance on testing, has lowered some barriers to feasible and effective diagnosis and care. Diagnostic and drug pricing is now a far less significant barrier to scale-up of HCV programs in LMICs than previously. Some LMICs, with limited public and donor funding available, have effectively utilized public-private partnerships or insurance schemes as a means to augment public programs and kick start testing and treatment.

Despite recent achievements, a wide range of prices exists across LMICs for testing and treatment with some countries paying high prices for commodities. Even within countries, the lack of mature public programs, multiple procurement channels, and the absence of coordinated activities across disease areas may lead to disparate and high prices. Diagnostic pricing often contains complex and difficult to discern components such that the ultimate cost to the program may be unknown. The lack of publicly available data on diagnostic prices and volumes and limited in-country information regarding DAA procurement budgets continues to hamper accurate forecasting. While these and other challenges persist in many countries, there are ways in which countries can seek opportunities to scale-up programs.

The increasing availability of cost effective, QA diagnostics and treatment options, in parallel with the simplified WHO guidance on testing, has lowered some barriers to feasible and effective diagnosis and care.

Increased domestic and international financing for HCV elimination is urgently needed to reach the 2030 target of HCV elimination globally.

Healthy children, that define the country's future, play basketball in Rwanda *© Christine McNab*

Going forward, countries can increase accessibility and affordability of diagnostics and drugs by accelerating in-country registration of WHO PQ'd diagnostics and treatment products. This will facilitate competition in the market and the availability of QA commodities to maintain a high quality of care. Countries can target a 12 week treatment course using WHO PQ'd SOF and DCV for less than US$100 per patient course, or even as low as US$60 per patient course if there is strong public commitment by government to HCV elimination over a defined period of time and procurement volumes are large as observed in Rwanda. Countries can also aim to optimize procurement volumes in order to maximize available procurement budgets. Identifying and reducing price mark-ups on products can help optimize supply-chain costs. A number of global pricing agreements by diagnostics suppliers and global procurement mechanisms for DAAs now exist, which can be leveraged to streamline procurement and lower prices respectively.

Recent experience has shown that, with strong political will and a public commitment to work towards HCV elimination within a reasonable timeframe, countries can secure diagnostic and treatment commodities to cure HCV for less than US$100 per patient, and in some cases lower than that. Nascent programs that are beginning to implement HCV treatment programs should consider the benefits of rapid scale up, in order to secure affordable pricing of diagnostics and drugs and decrease the need for ongoing costs by eliminating the disease in their countries.

In 2016 alone, as per WHO estimates, ~399,000 patients died due to HCV infection. If the world is able to achieve elimination (as defined by WHO) by 2030, we would have reduced mortality from HCV infection to less than ~140,000 deaths (65% reduction).

Increased domestic and international financing for HCV elimination is urgently needed to reach the 2030 target of HCV elimination globally.

Glossary

Expert Review Panel (ERP)	ERP is a risk based review by WHO PQ Team. It provides advice to allow for interim procurement, time limited for a maximum of one year, during which time the product should progress towards prequalification by WHO or approval by a Stringent Regulatory Authority (SRA).
Finished Dosage Form (FDF)	A final drug product, for example, tablet, capsule, solution, etc.
Freight on Board (FOB)	Export price which does not include shipping, customs and distributor associated costs. Usually there are in-country costs added to the FOB price which result in a higher final price to the buyer.
Medicines Patent Pool (MPP)	The Medicines Patent Pool (MPP) is a United Nations-backed public health organization that negotiates with patent holders for licenses on lifesaving medicines for LMICs. These licenses permit multiple suppliers to produce and distribute generic versions of patented medicines in developing countries. Competition between quality-assured generic pharmaceutical companies helps bring prices down and accelerates access to new treatments in developing countries.
Stringent Regulatory Authorities (SRA)	The national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) are considered as Stringent Regulatory Authority as per the GFATM Quality Assurance Policy for Pharmaceutical Products. Members include European Union member States, Japan, and the United States
WHO Prequalification Program	WHO Prequalification Program aims to ensure that diagnostics, medicines, vaccines and immunization-related equipment and devices for high burden diseases meet global standards of quality, safety and efficacy. This information is used by UN and other procurement agencies to make purchasing decisions.

Appendix

Appendix 1:

World Health Organization Recommended HCV Testing and Treatment Algorithm

Diagnostics Algorithm

The WHO recommends a simplified, two-step algorithm to diagnose HCV. First, a blood test to screen for HCV antibodies, using either a RDT or lab-based Immunoassay (IA) is performed. A positive antibody result indicates that the individual has been exposed to the pathogen. Although someone may have been exposed to a virus, and thereby possess antibodies against the pathogen, their immune system may have successfully cleared the virus from their body. A subsequent RNA nucleic acid VL test is therefore performed for individuals who screen positive for HCV antibodies to confirm active viremia prior to initiating treatment. All those who test positive for VL should be referred for treatment regardless of disease stage, though the duration of treatment may differ depending on the presence of cirrhosis.

When RNA testing is not available, quantification of HCV core Antigen (HCV cAg) by the lab-based Abbott ARCHITECT platform may serve as confirmation of viremia. Twelve weeks after completing a full treatment course, a VL test is recommended to provide a confirmation of HCV cure. Due to the sensitivity required for SVR12 however, HCV cAg testing is not recommended for confirmation of cure. The need to maintain VL testing for SVR12 is therefore essential and cannot be replaced solely through the use of quantification of cAg in the diagnostics cascade. In targeting elimination as set by the WHO, testing needs to be cost-effective and streamlined. Screening using rapid antibody tests and confirmation of viremia and cure by VL is therefore the method most often employed in elimination programs.

Previous diagnostic guidelines recommended the use of viral load monitoring at week 4 and required the determination of the viral genotype to enable appropriate treatment. The current diagnostics cascade, recommended by WHO in 2018, is simplified from the previous guidance. Assessing viral load at week 4 has been eliminated due to the lack of evidence correlating viral load at week 4 with those who achieve cure. In addition, when pan-genotypic DAAs are utilized in treatment, genotyping is not required, thereby significantly reducing the cost and complexity of testing.

Treatment Algorithm

Treatment for Adults (18 years or older)

For adults (18 years or older), WHO recommends pan-genotypic regimens including SOF and DCV (individual SOF + DCV or SOF/DCV FDC), SOF/VEL or G/P as potential options for treatment. Genotyping is not required. Liver fibrosis (identified through aspartate-to-platelet ratio index), comorbidities, pregnancy, and potential drug – drug interactions should be considered while identifying desired treatment regimen and length of treatment.

Treatment for children (under 12 years of age) and adolescents (12-17 years of age)

WHO recommends that in children under 12 years, treatment be deferred until they either reach 12 years or until DAA regimens are approved for those less than 12 years.

For adolescents (12-17 years), 2018 WHO HCV Treatment Guidelines recommend the use of genotype- specific regimens including SOF/LDV or sofosbuvir with ribavirin (SOF+RBV). Genotyping is required prior to determination of appropriate treatment regimen.

Urgent efforts are underway by WHO and partners to review pharmacokinetic and clinical data on SOF/DCV, the pan-genotypic regimen most widely used among adults, to determine whether it could be recommended for use among adolescents (12–17 years). The ability to treat all adolescents 12 years and older with the most widely used and least expensive DAA regimen is highly desirable.

More recent FDA approvals have expanded treatment availability beyond these guidelines: In August 2019 SOF/LDV and SOF+RBV received FDA approval for use down to age of 3 years or older, and in April 2019 G/P was approved for use in ages 12–17 years. The FDA approved in March 2020 the use of SOF/VEL, in combination with ribavirin, in children down to the age of six years.

Appendix 2:

DAA Originators and Licensing Agreements

Gilead, BMS, and AbbVie, the originators of key HCV drugs (DAAs), have agreements that allow them to license/sublicense their drugs to generic suppliers, in order to make drugs available at affordable prices in a large number of LMICs.

[List of eligible countries covered under the licensing agreements in Appendix 3].

Gilead: Gilead has directly licensed SOF, SOF/LDV, SOF/VEL and sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX) to generic suppliers. Fourteen generic suppliers have a license for Gilead's drugs. Indian generic suppliers listed in Exhibit 22 are permitted to sell Gilead licensed drugs across 105 countries, whereas Pakistani and Egyptian generic suppliers including Ferozsons (Pakistan), Magic Pharma (Egypt) and Pharmed (Egypt) are only permitted to manufacture and sell in their local markets.

BMS: In 2015, BMS signed a licensing agreement with Medicines Patent Pool (MPP) for sublicensing its originator daclatasvir (Daklinza) to generic suppliers. A hundred and twelve countries were included in this agreement and eight generic suppliers currently have a sublicense for the product. In 2019, BMS ceased distribution of Daklinza in US and European markets for commercial reasons. In Mar 2020, BMS announced that the marketing authorizations for Daklinza will be withdrawn or will be allowed to lapse in countries where the product no longer is routinely prescribed or where there are other therapeutic options available. This will affect some additional countries outside the licensed territory to the Medicines Patent Pool (MPP). Following the withdrawal/lapse of the marketing authorization in each country, the patents in that country will be allowed to lapse. In the interim period between the withdrawal/lapse of a marketing authorization and the patent expiry, BMS will not enforce its patents for Daklinza in that country.

Patients diagnosed with HCV in additional countries will soon have access to generic versions of daclatasvir. This list, with or without existing patents, includes Albania, Armenia, Belarus, Bosnia, Bulgaria, Chile, Colombia, Egypt, Jordan, Kazakhstan, Kosovo, Kyrgyz Republic, Lebanon, Macedonia, Malaysia, Mexico, Moldova, Montenegro, Peru, Romania, Serbia, Thailand, Tajikistan, Ukraine, Uruguay, and Venezuela.

Mylan's daclatasvir will replace BMS' Daklinza as the reference product for future WHO PQ/ ERP reviews of generic daclatasvir.

AbbVie: AbbVie signed a licensing agreement with MPP for G/P in November 2018, and Mylan was the first supplier to obtain the sublicense in Dec 2019 to manufacture G/P. It could take over two years for a generic supplier to develop and commercialize G/P after obtaining a sublicense to manufacture it, given that manufacturing the product and obtaining quality assurance can be a time-consuming process. BMS signed the licensing agreement with MPP for DCV in November 2015 and the first DCV WHO PQ filing was in Q2 2017. Developing generic G/P might take longer than developing generic DCV, as G/P is an FDC for which suppliers will have to develop two APIs and prove Bioequivalence (BE) for both. Developing DCV required development of only one API and proving its BE.

India, although an HCV high burden LMIC that is included in sublicense agreements for Gilead and BMS' HCV drugs, has not been included in the licensing agreement for G/P.

Exhibit 22: Generic Licensees for SOF, DCV, SOF/LDV, SOF/VEL, SOF/VEL/VOX, G/P

	DAA	# of countries included in license/sublicense agreement	% of countries included in the license/ sublicense agreement that are LMICs	Generic sub-licensees
Gilead	SOF SOF/LDV SOF/VEL SOF/ VEL/VOX	105 (Refer to Appendix 3.1 for list of countries)	72%	Aurobindo, Biocon, Cadila, Cipla, Ferozsons (Pakistan), Hetero, Laurus, Magic Pharma (Egypt), Mylan, Natco, Pharmed (Egypt), Sequent, Strides, Sun Pharma
BMS	DCV	112 (Refer to Appendix 3.2 for list of countries)	80%	Aurobindo, Beximco, Cipla, Hetero, Laurus Labs, Mylan, Natco, Zydus Cadila
AbbVie	G/P	96 (Refer to Appendix 3.4 for list of countries)	72%	Mylan

Note: Updated as of Jan 2020.

Source: Gilead's licensing agreement; BMS and MPP licensing agreement, AbbVie and MPP licensing agreement.

Appendix 3:

Countries included in the licensing agreements for DAAs

Appendix 3.1

COUNTRIES INCLUDED IN GILEAD'S LICENSING AGREEMENT FOR SOF, SOF/VEL, SOF/LDV, SOF/VEL/VOX				
Afghanistan	Cote d'Ivoire	Kenya	Nauru	Sri Lanka
Algeria	Cuba	Kiribati	Nepal	St. Vincent and the Grenadines
Angola	Djibouti	Kyrgyz Republic	Nicaragua	Sudan
Antigua and Barbuda	Dominica	Lao PDR	Niger	Suriname
Bangladesh	Egypt	Lesotho	Nigeria	Swaziland
Belarus	El Salvador	Liberia	North Korea	Tajikistan
Benin	Equatorial Guinea	Libya	Pakistan	Tanzania
Bhutan	Eritrea	Madagascar	Palau	Thailand
Bolivia	Ethiopia	Malawi	Papua New Guinea	Timor-Leste
Botswana	Fiji	Malaysia	Paraguay	Togo
Burkina Faso	Gabon	Maldives	Philippines	Tonga
Burundi	Gambia	Mali	Rwanda	Tunisia
Cambodia	Ghana	Marshall Islands	Samoa	Turkmenistan
Cameroon	Guatemala	Mauritania	Sao Tome & Pr.	Tuvalu
Cape Verde	Guinea	Mauritius	Senegal	Uganda
Central African Republic	Guinea-Bissau	Micronesia	Seychelles	Ukraine
Chad	Guyana	Mongolia	Sierra Leone	Uzbekistan
Comoros	Haiti	Morocco	Solomon Islands	Vanuatu
Congo, DR	Honduras	Mozambique	Somalia	Vietnam
Congo, Rep.	India	Myanmar	South Africa	Zambia
Cook Islands	Indonesia	Namibia	South Sudan	Zimbabwe

Appendix 3.2

COUNTRIES INCLUDED IN BMS AND MPP'S LICENSING AGREEMENT FOR DCV			
Afghanistan	El Salvador	Malawi	Seychelles
Algeria	Equatorial Guinea	Maldives	Sierra Leone
Angola	Eritrea	Mali	Solomon Islands
Azerbaijan	Ethiopia	Marshall Islands	Somalia
Bangladesh	Fiji	Mauritania	South Africa
Belize	Gabon	Mauritius	South Sudan
Benin	Gambia, The	Micronesia	Sri Lanka
Bhutan	Georgia	Mongolia	St Lucia
Bolivia	Ghana	Morocco	St Vincent and the Grenadines
Botswana	Grenada	Mozambique	Sudan
Burkina Faso	Guatemala	Myanmar	Suriname
Burundi	Guinea	Namibia	Swaziland
Cambodia	Guinea-Bissau	Nauru	Syria
Cameroon	Guyana	Nepal	Timor-Leste
Cape Verde	Haiti	Nicaragua	Togo
Central African Republic	Honduras	Niger	Tonga
Chad	India	Nigeria	Tunisia
Comoros	Indonesia	Niue	Turkmenistan
Congo, Democratic Republic	Iraq	Pacific Islands (Palau)	Tuvalu
Congo, Republic	Jamaica	Pakistan	Uganda
Cook Islands	Kenya	Panama	United Republic of Tanzania
Costa Rica	Kiribati	Papua New Guinea	Uzbekistan
Cote d'Ivoire	Korea, Dem. Rep.	Paraguay	Vanuatu
Cuba	Laos	Philippines	Vietnam
Djibouti	Lesotho	Rwanda	West Bank
Dominica	Liberia	Samoa	Yemen
Dominican Republic	Libya	Sao Tome and Principe	Zambia
Ecuador	Madagascar	Senegal	Zimbabwe

Appendix 3.3

COUNTRIES INCLUDED IN UNDP HEALTH PROCUREMENT MECHANISM				
Afghanistan	Cuba	Kenya	Nauru	Sudan
Algeria	Djibouti	Kiribati	Nepal	Suriname
Angola	Dominica	Korea DPR of	Nicaragua	Tanzania
Armenia	Egypt	Kyrgyz Republic	Niger	Thailand
Bangladesh	El Salvador	Lao PDR	Nigeria	Timor–Leste
Benin	Equatorial Guinea	Lesotho	Pakistan	Togo
Belarus	Eritrea	Liberia	Palau	Tonga
Bhutan	Eswatini (former Swaziland)	Libya	Papu New Guinea	Tunisia
Bolivia	Ethiopia	Madagascar	Paraguay	Turkmenistan
Bostwana	Fiji	Malawi	Philippines	Tuvalu
Burkina Faso	Gabon	Maldives	Rwanda	Uganda
Burundi	Gambia	Mali	Saint Vincent and the Grenadines	Ukraine
Cambodia	Ghana	Malaysia	Samoa	Uzbekistan
Cameroon	Guatemala	Marshal Islands	Sao Tome and Principe	Vanuatu
Cape Verde	Guinea	Mauritania	Senegal	Vietnam
Central African Republic	Guinea Bissau	Mauritius	Seychelles	Zimbabwe
Chad	Guyana	Micronesia	Solomon Islands	Zambia
Comoros	Haiti	Mongolia	Sierra Leone	
Congo	India	Morocco	Somalia	
Cook Islands	Indonesia	Myanmar	South Africa	
Cote d'Ivoire	Honduras	Mozambique	South Sudan	
Democratic Republic of the Congo	Kazakhstan	Namibia	Sri Lanka	

Appendix 3.4

COUNTRIES INCLUDED IN ABBVIE AND MPP'S LICENSING AGREEMENT FOR G/P			
Afghanistan	Equatorial Guinea	Maldives	Sao Tome and Principe
Angola	Eritrea	Mali	Senegal
Antigua and Barbuda	Eswatini	Marshall Islands	Seychelles
Bangladesh	Ethiopia	Mauritania	Sierra Leone
Belize	Fiji	Mauritius	Solomon Islands
Benin	Gabon	Micronesia	Somalia
Bhutan	Gambia	Morocco	South Africa
Bolivia	Georgia	Mozambique	South Sudan
Botswana	Ghana	Myanmar	Sri Lanka
Burkina Faso	Grenada	Namibia	Sudan
Burundi	Guinea	Nauru	Suriname
Cambodia	Guinea-Bissau	Nepal	Tanzania
Cameroon	Guyana	Niger	Timor-Leste
Cape Verde	Haiti	Nigeria	Togo
Central African Republic	Indonesia	Niue	Tunisia
Chad	Jordan	Pakistan	Turkmenistan
Comoros	Kenya	Palau	Tuvalu
Congo	Kiribati	Papua New Guinea	Uganda
Cook Island	Laos	Philippines	Vanuatu
Côte d'Ivoire	Lesotho	Rwanda	Vietnam
Democratic Republic of Congo	Liberia	Saint Kitts and Nevis	West Bank & Gaza
Djibouti	Libya	Saint Lucia	Yemen
Dominica	Madagascar	Saint Vincent & the Grenadines	Zambia
Egypt	Malawi	Samoa	Zimbabwe

Appendix 4:

Generic Supplier In-country Registrations in Viral Hepatitis High Burden Countries

(non-exhaustive list as of Q4 2019- Q1 2020)

	SOF (400 mg)	DCV (60 mg)	SOF/DCV FDC	SOF/LDV	SOF/VEL
Brazil					
Cambodia	Hetero, Mylan, Natco, ACI, Beximco, Cambodia Pharmaceutical Enterprise, Dyson, Eskayef, Faas, Future Pharmaceutical Industries, Genome, Genix, Getz, Global Pharmaceuticals, Hilton, Incepta, Natco , PharmEvo, Searle, Strides, Swiss Garnier	Hetero, Mylan, Cambodia Pharmaceutical Enterprise, Genix, Getz, Hilton, Incepta, Natco, Searle		Hetero, Mylan, Genix, Getz, Incepta, Natco, Swiss Garnier, Strides, Searle, Telpha	Hetero, Mylan, Beacon, Genome, Genix, Getz, Searle
Cameroon	Mylan	Mylan		Mylan	Mylan
China					
Colombia	Cipla				
Egypt	Hetero*				
Ethiopia	Hetero, Cipla, Eva Pharma, Strides, Mylan	Eva Pharma, Mylan		Gilead	
Georgia					
India	All Licensees	All Licensees	All Licensees	All Licensees	All Licensees
Indonesia	Hetero, Mylan, Natco, Strides	Mylan, Natco, Hetero		Hetero	
Kyrgyzstan	Hetero	Hetero		Hetero, Mylan	Hetero
Malaysia	Hetero	Hetero			
Mongolia	Hetero, Mylan	Mylan		Hetero, Mylan	
Morocco	Galencia, Pharma 5	Galencia, Pharma 5		Mylan	Mylan

	SOF (400 mg)	DCV (60 mg)	SOF/DCV FDC	SOF/LDV	SOF/VEL
Myanmar	Hetero, Mylan, Natco, Unipharm, Intec, Genix, Top Prime, Zlfam, Getz, Pharmevo, Incepta	Hetero, Getz, Julphar	Mylan, Incepta, Top Prime	Hetero, Mylan, Natco, Genix, Getz	Hetero, Mylan, Genix, Getz
Nepal	Hetero			Hetero (Temporary permit)	Hetero (Temporary permit)
Nigeria	Cipla, Hetero, Mylan	Hetero, Mylan	Mylan	Mylan	Mylan
Pakistan	Cipla, Mylan	Mylan		Mylan	Mylan
Peru	Hetero				
Philippines	Mylan, Hetero	Mylan		Mylan	
Rwanda		Hetero		Natco	
Sierra Leone					
South Africa					
Tanzania	Cipla	Hetero		Hetero	Mylan
Thailand	Hetero, Mylan			Mylan	Mylan
Uganda	Hetero, Mylan		Mylan	Mylan, Hetero	
Ukraine	Hetero	Hetero		Hetero	
Uzbekistan	Hetero	Hetero, Mylan		Hetero, Mylan	Hetero
Vietnam	Mylan, Natco, Strides, Atra, Ampharco U.S.A, Hera Biopharmaceutical, BV Pharma, Pymepharco, Cipla, Minh Hai, Medbolide	Hetero (SIQ), Mylan, BRV Healthcare, Hera Biopharmaceutical		Mylan, Natco, Hera Biopharmaceutical, BV Pharma, Pymepharco, Ampharco U.S.A, Minh Hai	Hetero (SIQ), Mylan
Zimbabwe	Hetero, Cipla, Mylan	Mylan		Hetero	

**Hetero is manufacturing product locally in Egypt*

Source: Hetero (Apr 2020), Cipla (Jan 2020), Mylan (Apr 2020), CHAI, Coalition PLUS, World Hepatitis Alliance and its members.

Appendix 5:

Member states of PAHO's Strategic Fund (June 2018)

MEMBER STATES OF THE STRATEGIC FUND		
Argentina	Ecuador	Panama
Bahamas	El Salvador	Paraguay
Barbados	Guatemala	Peru
Belize	Grenada	Dominican Republic
Bermuda	Guyana	Saint Kitts and Nevis
Bolivia	Haiti	Saint Lucia
Brazil	Honduras	Saint Vincent and the Grenadines
Chile	Turks and Caicos Islands	Suriname
Colombia	British Virgin Islands	Trinidad and Tobago
Costa Rica	Jamaica	Uruguay and Venezuela
Cuba	Nicaragua	

Appendix 6:

Guidance for procurement agents in obtaining visibility of diagnostic cost components

The following questions and considerations may be valuable for developing an understanding of the cost components which make up the final price to programs.

- Do the itemized costs which appear on the invoice match the expected prices based on the procurement agreement?
- Are you accessing the global ceiling prices for viral load tests through the procurement contract?
- If the specific inclusions for each cost component on the invoice is not known, you are encouraged to enquire with the distributor to gain clarity of which incoterms are included for each component.
- It is valuable to understand which cost components are flexible. For example, are local taxes or import tariffs avoidable based on the compassionate use of the products?
- Are the distributor mark-ups/margins reasonable? To understand what mark-up is reasonable, it may be helpful to benchmark off other programs such as HIV or TB.

Appendix 7:

Volumes and Pricing of DAAs exported from India to LMICs (2016- 2019)

		# of bottles exported				Weighted average price per bottle (USD)			
Country	**Drug**	**2016**	**2017**	**2018**	**2019**	**2016**	**2017**	**2018**	**2019**
AFGHANISTAN	DCV		11,000				$21		
BANGLADESH	SOF				300				$18
	DCV				450				$11
BENIN	SOF/LDV				50				$59
BOLIVIA	DCV				120				$15
BURUNDI	SOF				300				$100
	SOF/VEL			240	770			$101	$102
	SOF/LDV	600				$104			
CAMBODIA	SOF	3,620	2,094	2,542	1,289	$122	$40	$45	$28
	DCV	500	1,550	3,000	2,550	$40	$31	$30	$24
	SOF/DCV FDC				90				$40
	SOF/VEL			700	2,525			$103	$85
CAMEROON	SOF	1,596	3,050	250		$46	$87	$84	
	SOF/VEL			1,642				$141	
	SOF/LDV	240				$331			
COTE D'IVOIR	SOF	144				$178			
	SOF/VEL			30,000				$134	
DEMOCRATIC REPUBLIC OF THE CONGO	SOF/VEL				144				$149

		# of bottles exported				Weighted average price per bottle (USD)			
Country	**Drug**	**2016**	**2017**	**2018**	**2019**	**2016**	**2017**	**2018**	**2019**
EAST TIMOR	SOF				120				$18
	DCV				180				$11
	SOF/VEL				480				$86
EGYPT	SOF	26,582	140,093	296,079	119,020	$70	$15	$12	$13
INDONESIA	SOF		6,000	9,700	12,600		$17	$72	$85
	DCV			12,600	298			$30	$30
KENYA	SOF	450				$244			
	SOF/LDV		100	50	3,600		$188	$34	$58
KYRGYZSTAN	SOF	1,868	790	2,251	3,329	$112	$50	$51	$37
	DCV		300	6,498			$25	$28	
	SOF/VEL				1,870				$77
	SOF/LDV	1,000		1,002	1,755	$125		$74	$50
LAOS	SOF			150				$40	
	SOF/DCV FDC				300				$36
	SOF/VEL				1,350				$71
MAURITANIA	SOF	660				$121			
	DCV	660				$63			
MOLDOVA	SOF/VEL				400				$85
MONGOLIA	SOF	1,000	300		300	$155	$49		$41
	DCV		500		300		$20		$17
	SOF/LDV	19,668	30,431	32,570	2,294	$76	$53	$52	$55
MOROCCO	SOF/LDV	325				$212			

		# of bottles exported				Weighted average price per bottle (USD)			
Country	**Drug**	**2016**	**2017**	**2018**	**2019**	**2016**	**2017**	**2018**	**2019**
MYANMAR	SOF	18,155	12,545	44,061	29,418	$71	$45	$28	$18
	DCV	17,900	4,519	9,806	3,755	$24	$27	$25	$23
	SOF/DCV FDC			3,000	1,726			$36	$27
	SOF/VEL		3,300	5,436	68,161		$117	$164	$80
	SOF/LDV	7,012	4,484			$111	$89		
NEPAL	SOF	2,232				$121			
	DCV	70		200		$45		$32	
	SOF/VEL				800				$84
	SOF/LDV		576				$120		
NIGERIA	SOF	4,720	5,040		1,000	$103	$49		$18
	DCV	300		400	1,000	$59		$27	$12
	SOF/VEL			300	75			$139	$113
PAKISTAN	SOF	73,386	100,002	104,504	43,080	$35	$16	$11	$22
	DCV	9,605	27,000	25,067	51,260	$42	$12	$9	$3
	SOF/VEL				25,581				$42
PHILIPPINES	SOF			13,765	3,442			$40	$40
	DCV				4,135				$15
	SOF/VEL				1,000				$90
RWANDA	SOF				2,996				$16
	DCV				117,898				$7
SRI LANKA	SOF		100				$101		
SYRIAN ARAB REPUBLIC	DCV			100				$25	
TAJIKISTAN	SOF	50		50		$40		$30	
	SOF/VEL				848				$71
	SOF/LDV	515	621	1,584	864	$100	$59	$49	$52

		# of bottles exported				Weighted average price per bottle (USD)			
Country	**Drug**	**2016**	**2017**	**2018**	**2019**	**2016**	**2017**	**2018**	**2019**
TUNISIA	SOF				240				$41
UKRAINE	SOF				84,698				$20
	DCV				21,234				$10
	SOF/VEL				7,475				$90
	SOF/LDV				9,648				$30
UZBEKISTAN	SOF	1,172	9,007	1,558	41,545	$69	$19	$34	$25
	DCV		6,037	3,236	50,145		$45	$40	$13
	SOF/VEL				9,657				$93
	SOF/LDV	9,815	18,512	7,162	5,101	$78	$55	$49	$54
VIETNAM	SOF	46,392	8,239	12,558	2,168	$86	$59	$43	$75
	DCV	11,750	8,500	1,188	2,162	$43	$36	$36	$36
	SOF/VEL		23,890	8,800	8,141		$118	$115	$90
	SOF/LDV		13,954	4,012	8,720		$95	$59	$65
ZIMBABWE	SOF/LDV	70				$273			

Note: Only orders above 50 bottles considered; each bottle has 28 pills; Public and private sector orders both included; Wt. avg. price is weighted average of volumes of all orders >50 bottles and their respective price per bottle.

Source: India Import-Export Database; Country categorization into LMICs based on the World Bank categorization June 2018.

Appendix 8:

Data Sources

CHAI has relied upon three primary data sources for the analysis on the report.

INDIA IMPORT EXPORT DATA

The India Import Export Data provides details on the volumes and prices of drugs exported from India to the rest of the world. As shown in Exhibit 23 below, the data has relevant details on date of export, importer name, exporter name, the product exported and the country to which it was exported, size of the export order, and the freight on board price. FOB prices are the prices at which the supplier exports the drug from the country. These prices do not include shipping, customs, storage and distributor-associated costs. Usually there are in-country costs added to the FOB price, resulting in a higher final price to the buyer.

EXHIBIT 23: SAMPLE OF INDIA IMPORT EXPORT DATA

DATE	IMPORTER	EXPORTER	PRODUCT	DESTINATION	QUANTITY	UNIT	UNIT RATE (USD)	FOB VALUE (USD)
2019/1/18	AGP LIMITED	MYLAN	MYHEP ALL SOFOSBUVIR AND VELPATASVIR FIL	PAKISTAN	8594	PAC	49.64	426639
2019/3/14	OOO ASTOR ALLIANCE	HETERO	SOFGEN (55020 TABS) SOFOSBUVIR 400MG TAB	UZBEKISTAN	1965	PAC	34.13	67070.70

The India import export data has been used across the report to calculate the uptake of key generic DAAs from India, the weighted average FOB price per bottle of key DAAs, and weighted average FOB price per bottle of key DAAs for different order sizes. The data has also been used to compare the FOB price with the in-country price to get a sense of the in-country price mark-ups on DAAs. The analysis has excluded orders for less than 50 bottles as these orders are potentially placed by individuals or small pharmacies and have a high price per bottle, tending to skew the analysis. While the data provides a directional understanding of treatment uptake across countries, it does have limitations. The data can be incomplete, and does not account for drugs that are manufactured in other countries such as Pakistan and Egypt. Hence, the analyses may not be complete or an accurate representation of the global DAA market. The quality of the product is not included (i.e. SRA approved/WHO PQ'd/ ERP reviewed vs. locally approved product), hence, higher quality product typically sold at higher prices may skew prices upward or large number of locally approved products may skew prices downward.

CHAI'S COUNTRY TEAMS, GLOBAL PARTNERS AND STAKEHOLDERS

The absence of public diagnostics databases containing information such as pricing and test volumes meant that CHAI was entirely dependent on global partners and CHAI country teams for testing information. CHAI is grateful to its global partners including Treatment Action Group, FIND, Coalition PLUS, World Hepatitis Alliance, Treat ASIA/ amfAR for providing in-country information on prices and product registered in country for countries where CHAI does not have an HCV program. Our peers from these organizations shared the in-country data that they had available through primary research and their understanding of the market. In some cases, they connected us with their relevant individuals in their network who are based in-country and would have the relevant information available.

Data for CHAI program countries including India, Rwanda, Nigeria, Cambodia, Indonesia, Vietnam, Myanmar and Ethiopia was sourced from CHAI program country teams. The country teams were supported by their MoH counterparts in obtaining the relevant information.

The in-country prices have been used to compare prices across high-burden countries for key DAAs. These prices have also been used to compare the FOB price with the final in-country price in public/ private sector.

The approach has its limitations in understanding the DAA prices in countries that do not have a public program. This is due to the variability of prices in the private sector and lack of perfect knowledge on the range of prices offered across pharmacies in the private sector.

GENERIC DRUG SUPPLIERS

CHAI gathered information on in-country registration status of WHO PQ'd/ERP reviewed generic DAAs from suppliers including Hetero, Mylan, and Cipla.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