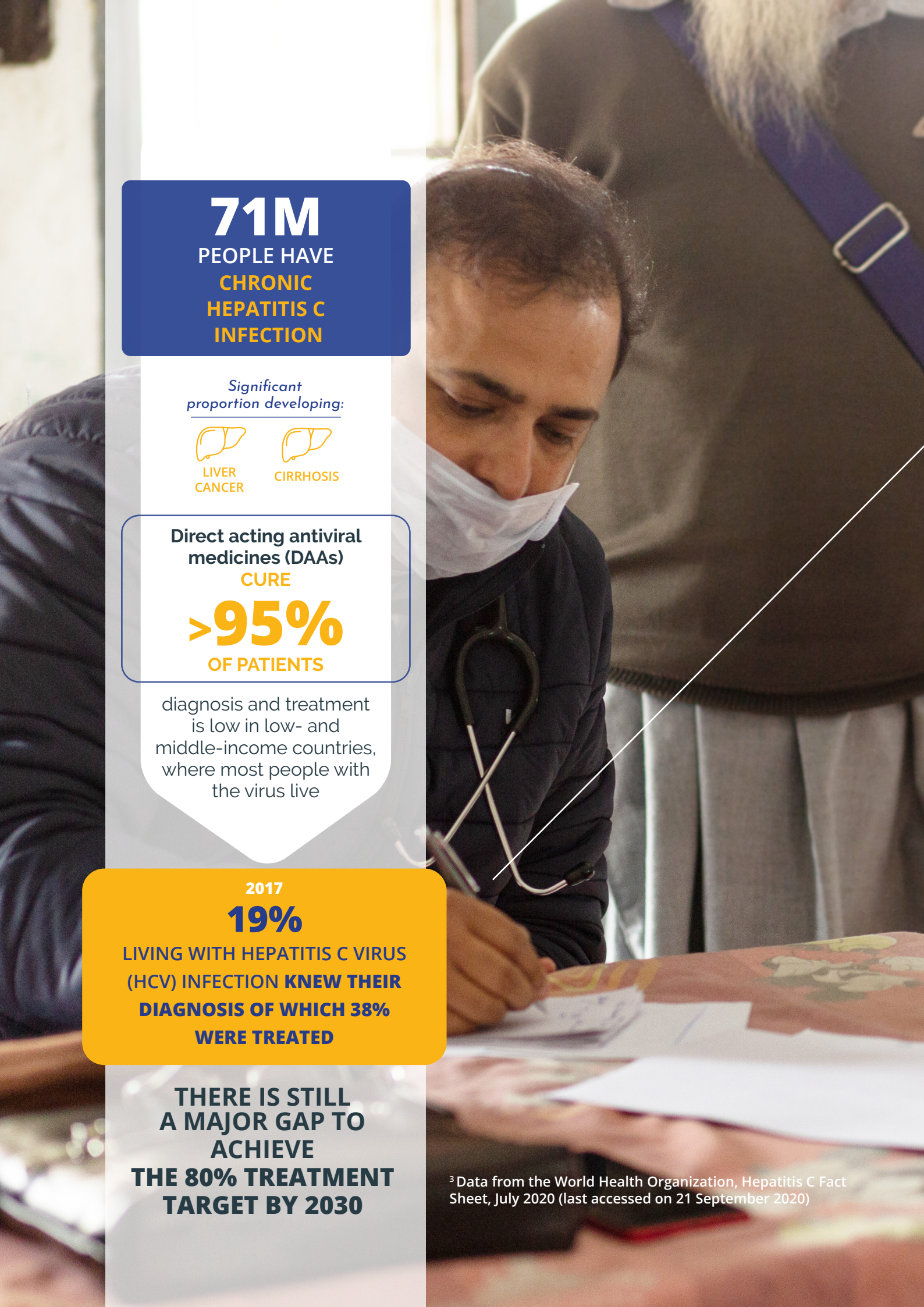


71M
PEOPLE HAVE
CHRONIC HEPATITIS C INFECTION

Significant proportion developing:

LIVER CANCER

CIRRHOSIS

Direct acting antiviral medicines (DAAs)
CURE
>95%
OF PATIENTS

diagnosis and treatment is low in low- and middle-income countries, where most people with the virus live

2017
19%
LIVING WITH HEPATITIS C VIRUS (HCV) INFECTION **KNEW THEIR DIAGNOSIS OF WHICH 38% WERE TREATED**

THERE IS STILL A MAJOR GAP TO ACHIEVE THE 80% TREATMENT TARGET BY 2030

[3] Data from the World Health Organization, Hepatitis C Fact Sheet, July 2020 (last accessed on 21 September 2020)

HEPATITIS C

HEPATITIS C

Fighting India's Silent Epidemic

SIMON BEDDOE

Simon Beddoe has been working with drug use & harm reduction programmes for 18 years. He is the former President of the Indian Drug Users' Forum and works on community-centric, human rights-based health programmes for people who use drugs. He is an advocate for harm reduction and wants to end the criminalisation of drug users. He was recently elected as Chairperson of ANPUD Asian Network of People Who Use Drugs.

They were doing an annual routine blood test – they do 20 or 30 tests for a thousand rupees (approx. USD 14). My wife was doing these, and she insisted I do it too, because I had been losing a lot of weight rapidly and, just out of curiosity, I said ok," said Simon Beddoe from India. "The result was really a shock for me. I freaked out, my wife freaked out. I didn't expect it. I last presented as a drug user 15 years ago. Till today, I haven't had the audacity to share with my extended family, like my brothers, sisters, because it's too freaky for them to imagine that I had hepatitis C, that I almost died and that I still have what's left of a liver cirrhosis.

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) that can result in acute and chronic hepatitis with a range of illness – from mild disease to life-threatening condition. Hepatitis C is also a major cause of liver cancer. Globally, an estimated 71 million people have chronic hepatitis C virus infection[3]. And in 2016, approximately 399,000 people died from the disease[3], mostly from cirrhosis and primary liver cancer. In India, an estimated 6-12 million people are infected with HCV[4], including 37.2% of people who inject drugs (PWID)[5]. Direct-acting antiviral (DAA) medicines recommended by the World Health Organization can cure

more than 95% of HCV-infected people, yet in 2017, as little as 7% of people with hepatitis C infection received treatment. Affordability of these medicines remains a critical bottleneck.

Only over the last couple of years a few government hospitals have slowly started shifting from PEG-Interferon to DAAs. I started talking to people and doctors to ask how I could access these effective medicines. Then reality struck. DAAs costs nearly 15,000 rupees per month (USD 210). Even though I was earning a good salary as a project manager, I still couldn't afford the money needed to pay for my own DAAs. Many people in India don't even earn that much money in a month.

I was lucky enough to get information that it was being given free in one of the government hospitals and then started my journey of engaging directly with the Indian healthcare system. After spending hours and sometimes days in hospital queues, hunger pangs and countless stockouts, I did avail free treatment. Initially, I didn't feel like I was getting better. For the first couple of months I was very depressed, I wasn't feeling too good. But things improved after the first couple of months.

Now, my mission is to push for all PWIDs in India to be diagnosed and treated. And thankfully, the National HCV programme has put in the numbers we suggested based on our evidence. So, in India now we have about 40% of PWIDs who are HCV-positive. Some 80,000 PWIDs, who were just like me, are going to be treated for free in the next two years – so it's really exciting. We have put the target of 40,000 PWIDs on free DAAs in year one – and that's the focus right now. It (hepatitis C) just broke me as a worker but it kind of gave me a renewed purpose, especially for this agenda because up until I was diagnosed, the agenda was more holistic harm reduction in every facet, in every component – but when I was diagnosed, treated and cured, I thought this specific agenda certainly deserves more focus.

There is a long way to go. Elimination of viral hepatitis is possible and 65% reduction in hepatitis C-related deaths by 2030 is achievable, but only if the recommended lifesaving medicines are affordable for everyone, everywhere.

[4] National Action Plan combating viral hepatitis in India, Ministry of Health and Family Welfare, Government of India, 2019

[5] High burden of HCV disease and poor access to HCV services among people who inject drugs in India: A cross-sectional study among 14,481 drug users across India

MPP's ROLE IN IMPROVING **HEPATITIS C TREATMENT ACCESS**

8 GENERIC COMPANIES

have signed sublicences with MPP to develop, manufacture and supply DAAs in low- and middle-income countries.

HEPATITIS C

daclatasvir (DAC) 30 mg and 60 mg

Daclatasvir is a DAA and an inhibitor of the HCV NS5A protein. The combination of daclatasvir with sofosbuvir has been recommended by WHO as a pan-genotypic regimen for adult patients with chronic hepatitis C. Daclatasvir 60 mg is given once daily, and the dose can be adjusted to 30 mg or 90 mg to address drug-drug interaction with certain medicines required for managing co-morbidities.

As of December 2019, five companies were developing the two products, of which Cipla, Hetero and Mylan received WHO prequalification and Laurus Labs received approval from the Expert Review Panel (ERP) coordinated by the Global Fund

The territory covered by MPP's daclatasvir licence agreement is 112 countries. Generic DAC is approved in 28 countries, supplied in 25 countries and filed in another 23 countries.

Cipla HETERO LAURUS Labs Knowledge . Innovation . Excellence Mylan

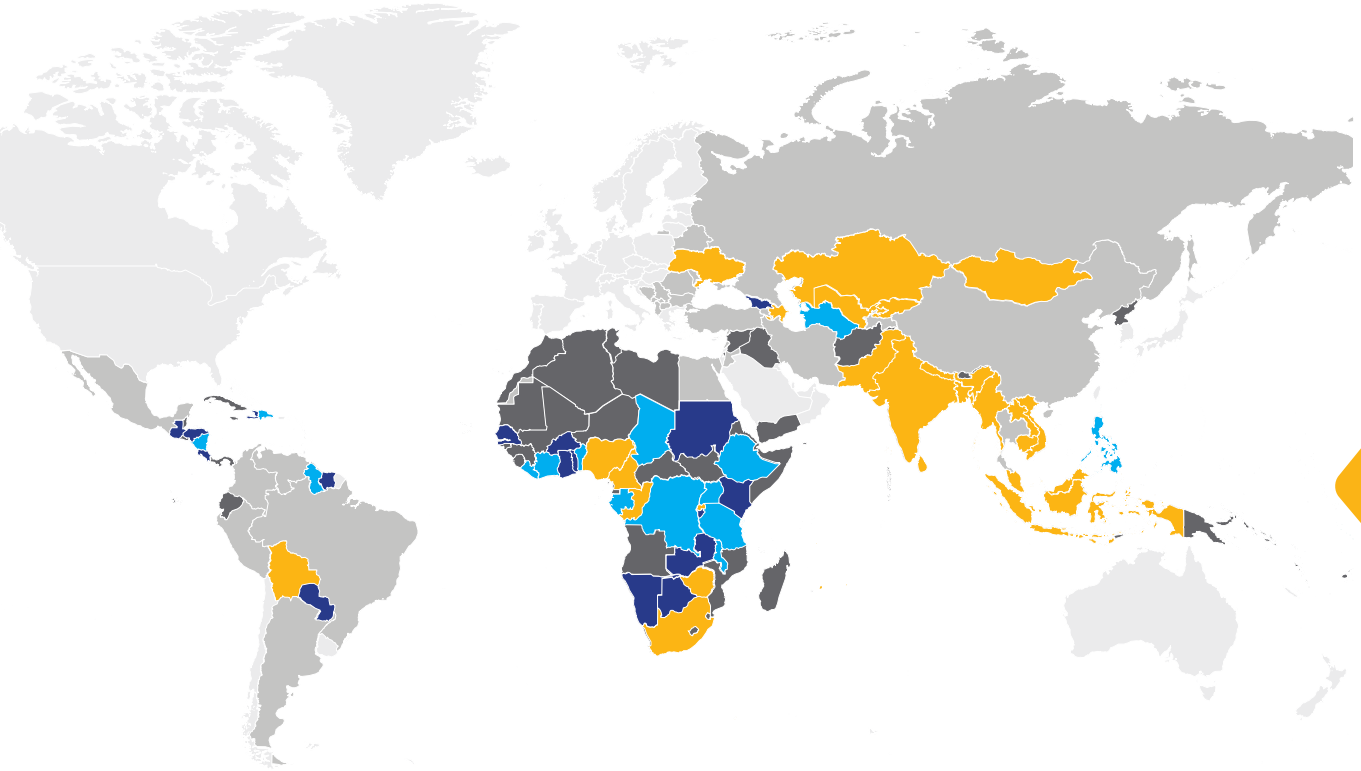
daclatasvir + sofosbuvir (DAC + SOF) 60/40 mg

DAC+SOF is a fixed-dose combination DAA regimen recommended by WHO as once-daily treatment of HCV in adults where DAC can be adjusted from 60 mg to 90 mg to compensate for drug-drug interactions with certain medicines required to manage co-morbidities.

As of December 2019, three MPP licensees were developing DAC + SOF combination, of which Cipla received WHO prequalification for the co-blister pack and Mylan received approval from the Expert Review Panel (ERP) coordinated by the Global Fund.

The territory covered by MPP and other relevant licences for this product is 97 countries. Generic DAC + SOF is approved in seven countries, supplied in five and filed in another 15 countries.

Cipla Mylan

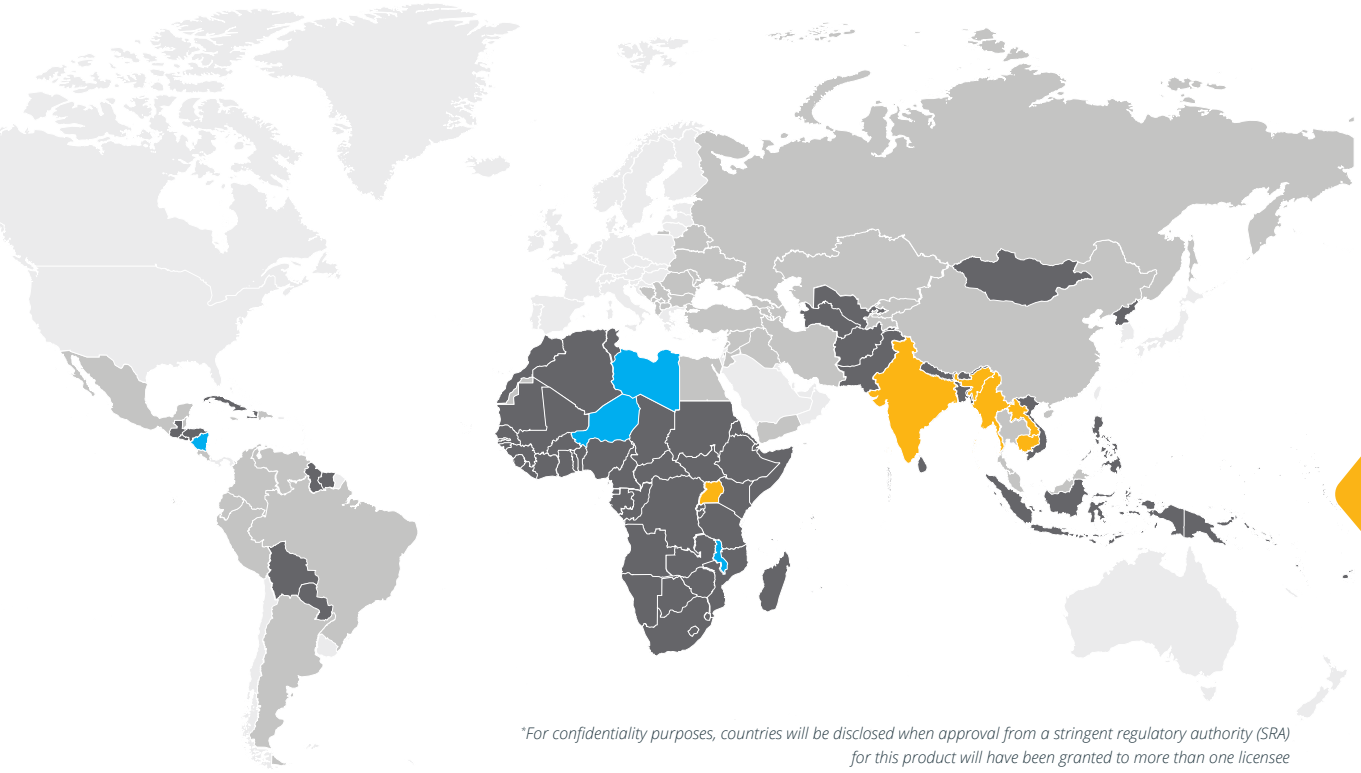


COVERED TERRITORY
112
COUNTRIES

FILED IN
23
COUNTRIES

APPROVED IN
28
COUNTRIES

SUPPLIED IN
25
COUNTRIES



COVERED TERRITORY
97
COUNTRIES

FILED IN
15
COUNTRIES*

APPROVED IN
7
COUNTRIES

SUPPLIED IN
5
COUNTRIES

For confidentiality purposes, countries will be disclosed when approval from a stringent regulatory authority (SRA) for this product will have been granted to more than one licensee

Data as of December 2019, by MPP sublicensees.

FIRST SUBLICENCE AGREEMENT FOR GLECAPREVIR/ PIBRENTASVIR (G/P)

In December 2019, MPP signed a sublicence agreement and partnered with Mylan to develop, manufacture and supply the first generic version of glecaprevir/pibrentasvir (G/P) – a WHO-recommended treatment for hepatitis C virus infections.

G/P is the only all oral, once-daily pan-genotypic combination regimen recommended by WHO that is currently not available as a generic medicine. The two organisations have entered an agreement to undertake G/P manufacturing henceforth and boost the supply to make it accessible to hepatitis C patients.

In November 2018, MPP had signed a royalty-free licence agreement with patent holder AbbVie to enable quality-assured manufacturers to develop and sell generic medicines containing G/P in 96 low- and middle-income countries and territories at affordable prices.

HEPATITIS C