



HEPATITIS C

*Direct-acting
antiviral medicines
can cure more than
95% of patients
**but access to diagnosis
and treatment is low**
especially in low- and middle-income
countries, where the vast majority
of people with the virus live¹⁰*

“When my father became ill suddenly in 2001, he had never heard of hepatitis C, nor had anyone else in my family. We had no idea what was happening. He passed away three months after first entering the hospital. The doctors did not really explain how many months the treatment would take, nor how it would work, and the medicines were very expensive for us at the time.

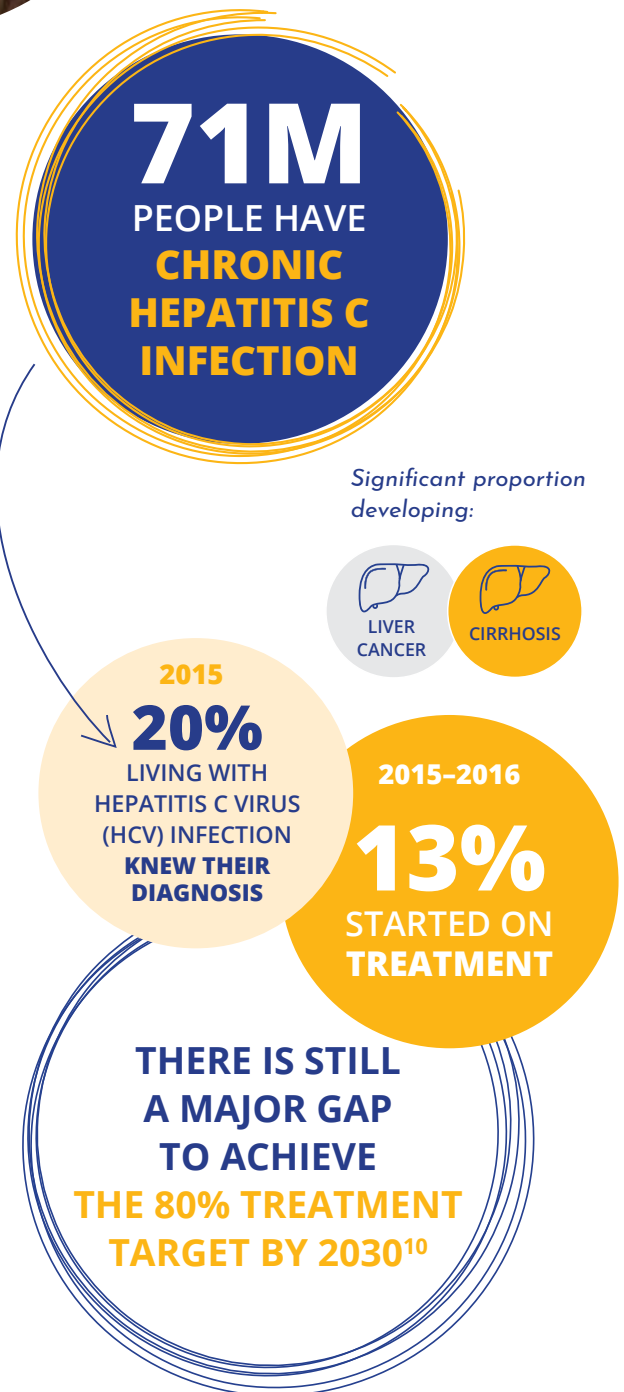
This drove me to learn more about the disease. I only knew that it was serious and that the existing medications were inadequate, even toxic. I had also started noticing that something was happening in my neighbourhood: people around me, including friends, showed signs of hepatitis symptoms.

Now, 17 years later, I know what this disease is and what causes it. And I have since learned that my father died of intolerance to interferon, the drug used at the time to treat hepatitis C. Fortunately, hepatitis C medicines have improved since then and have fewer side effects.

The Medicines Patent Pool’s public health-oriented licences contribute to scaling up access to quality-assured generic medicines and combinations in low- and middle-income countries, e.g. for daclatasvir (licence agreement with Bristol-Myers Squibb) and sofosbuvir (licence agreement with Pharco Pharmaceuticals). To make sure that most people can access them, hepatitis C medicines must become part of public health programmes and strategies. We should focus on making this happen.”



GITEN KHWAIRAKPAM,
Community and Policy Programme Manager, amfAR/TREAT Asia programme, Bangkok, and member of the Medicines Patent Pool’s Expert Advisory Group for hepatitis.



¹⁰ World Health Organization, Key Facts (website accessed on 28 February 2019)

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THE MPP'S ROLE IN IMPROVING HEPATITIS C TREATMENT ACCESS

Ten generic companies have signed sublicences with the MPP to develop, manufacture and sell DAAs in LMICs.

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 is given 60mg once daily, and the dose can be adjusted to 30mg or 90mg to address drug-drug interaction with certain medicines required for managing co-morbidities.

daclatasvir 30mg and 60mg

As of December 2018, six companies were developing the two products, of which Cipla, Hetero and Mylan had approval from the ERP led by WHO.

The territory covered by the MPP licence is 112 countries. Generic DAC is approved in 25 countries, sold in 13 countries and filed in another 29 countries.

Cipla



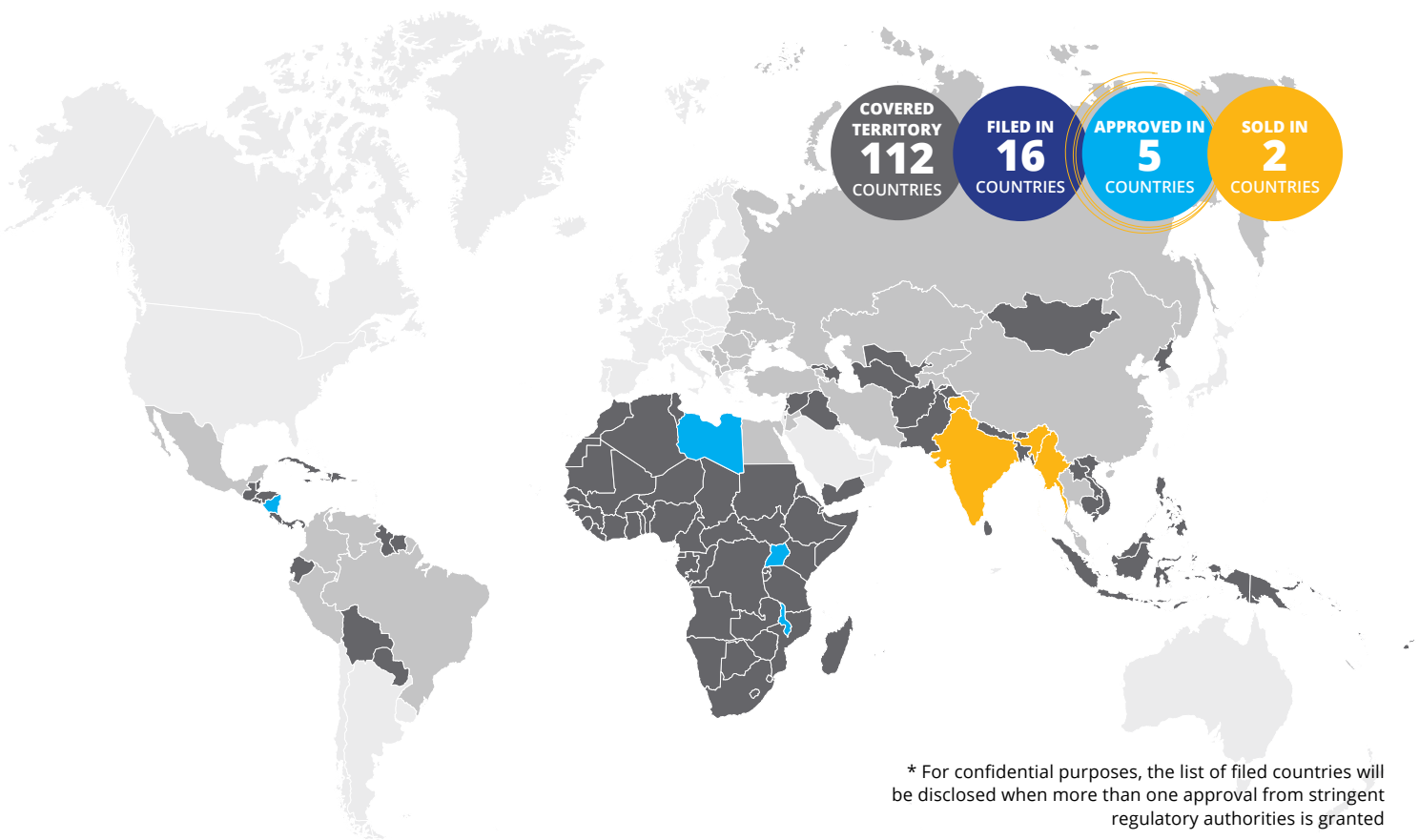
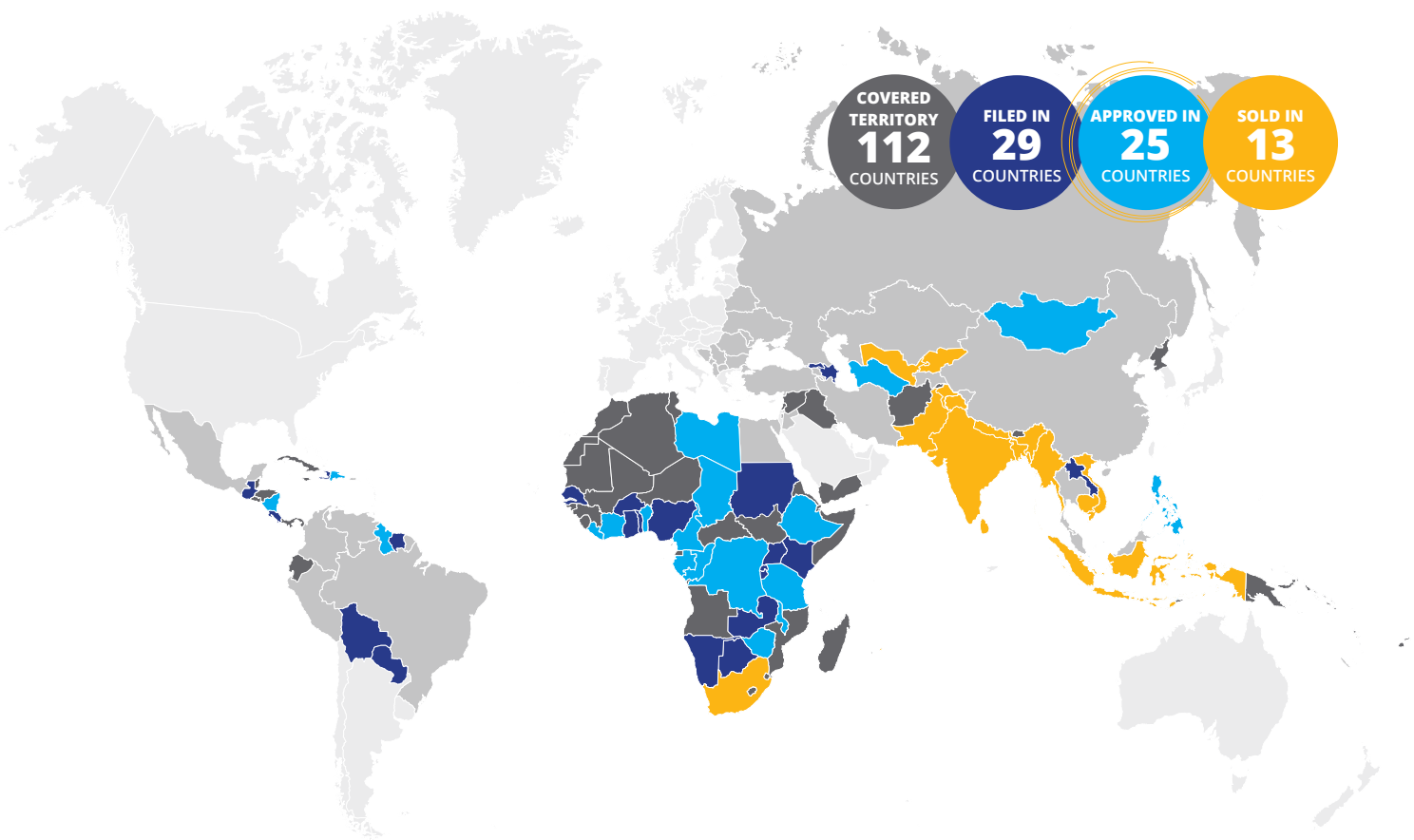
Mylan

daclatasvir + sofosbuvir (DAC + SOF)

As of December 2018, two MPP licensees were developing DAC + SOF combination, of which Cipla received ERP approval for the co-blister pack.

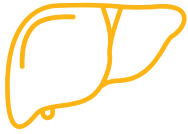
The territory covered by the MPP licence is 112 countries. Generic DAC + SOF is approved in five countries, sold in two and filed in another 16 countries.

Cipla



* For confidential purposes, the list of filed countries will be disclosed when more than one approval from stringent regulatory authorities is granted

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AGREEMENT WITH ABBVIE FOR KEY HEPATITIS C TREATMENT

In November, the MPP signed a new, royalty-free licence agreement with AbbVie for **glecaprevir/pibrentasvir (G/P)** – a WHO-recommended treatment for people living with HCV. The licence allows quality-assured manufacturers to develop and sell generic medicines containing G/P in 99 LMICs and territories at affordable prices, accelerating access to and treatment scale-up with a key pan-genotypic regimen. The agreement was launched at the American Association for the Study of Liver Diseases, The Liver Meeting 2018 in San Francisco.

G/P is an all-oral, once-daily, pan-genotypic combination regimen and was originally approved in 2017. It has achieved high cure (SVR12) rates of 98% in treatment-naïve non-cirrhotic patients across all six genotypes of the virus. It is recommended by WHO as a first-line treatment for eight weeks in treatment-naïve non-cirrhotic patients. Treatment-naïve patients with compensated liver cirrhosis require a 12-week treatment course.

The regimen is also indicated for use in HCV patients with any degree of renal impairment, including patients on dialysis.

“Central to our vision at AbbVie is developing therapies, such as our pan-genotypic HCV treatment, for the most serious diseases and providing access to those treatments. We are pleased to have reached today’s agreement with the MPP.”

Laura Schumacher

Executive Vice President, External Affairs, General Counsel and Corporate Secretary, AbbVie





"The new agreement is an important step towards achieving elimination of hepatitis C worldwide. We urge national governments to take action now to make such curative treatments available for the millions of people in need."

Gottfried Hirschall

*Director of Department of HIV and Global Hepatitis Programme,
World Health Organization*

"The Government of Pakistan warmly welcomes the agreement between the Medicines Patent Pool and AbbVie to expand access to glecaprevir/pibrentasvir – a very important therapy for the treatment of HCV – into territories including Pakistan. The HCV burden in Pakistan is endemic, affecting over eight million of our country's population, and the prevention and treatment of HCV is a national priority.

This agreement will considerably aid our efforts and, ultimately, accelerate the permanent elimination of the hepatitis C"

Aamer Mehmood Kianai

*Federal Minister
Ministry of National Health Services, Regulations and Coordination,
Government of Pakistan*

"Claiming over one million lives each year, viral hepatitis is one of the world's major public health challenges and disproportionately affects people living in LMICs. Therefore, access to safe, quality-assured treatments, affordable for all, has to be the fundamental aim of the public health community. This is a big step in that direction. The next step is to see more territories included in the agreement.

Each step makes the dream of hepatitis C elimination more real."

Raquel Peck

*CEO,
World Hepatitis Alliance*