

EXPANDING ACCESS TO HIGH-QUALITY GENERIC MEDICINES IN LOW-AND MIDDLE-INCOME COUNTRIES THROUGH VOLUNTARY LICENSING:

THE MEDICINES PATENT POOL'S CONTRIBUTION TO THE HEPATITIS C RESPONSE

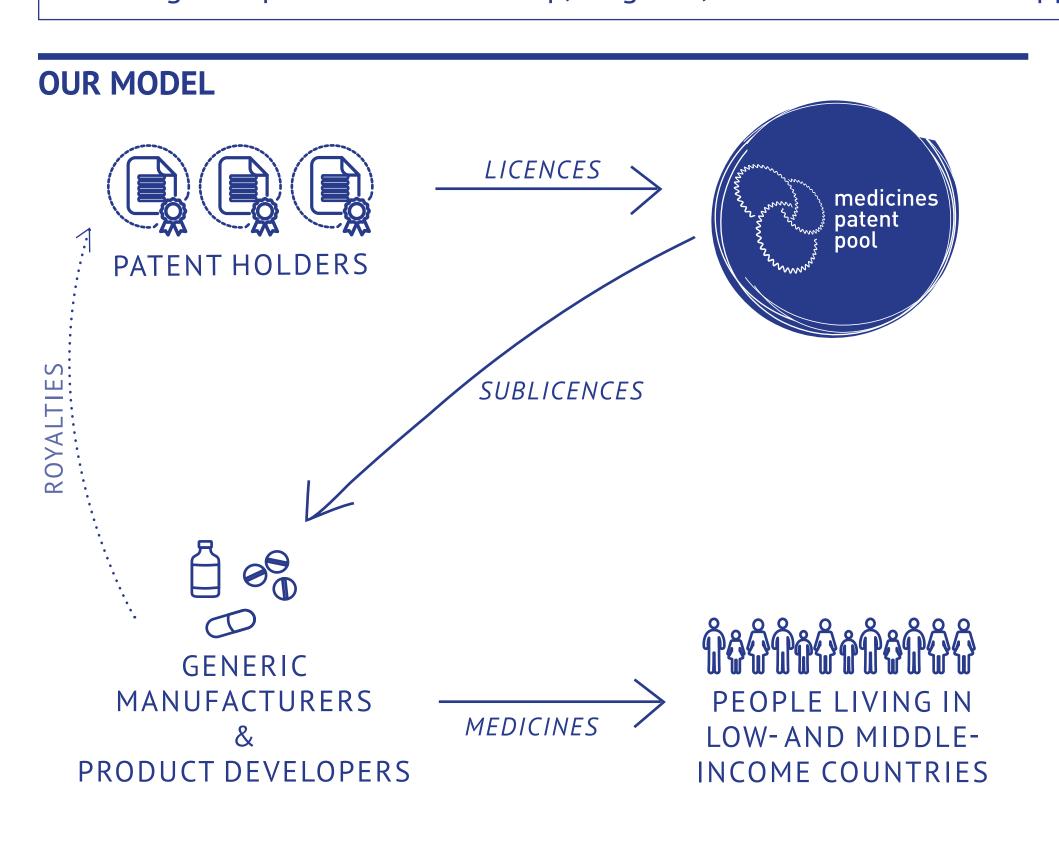
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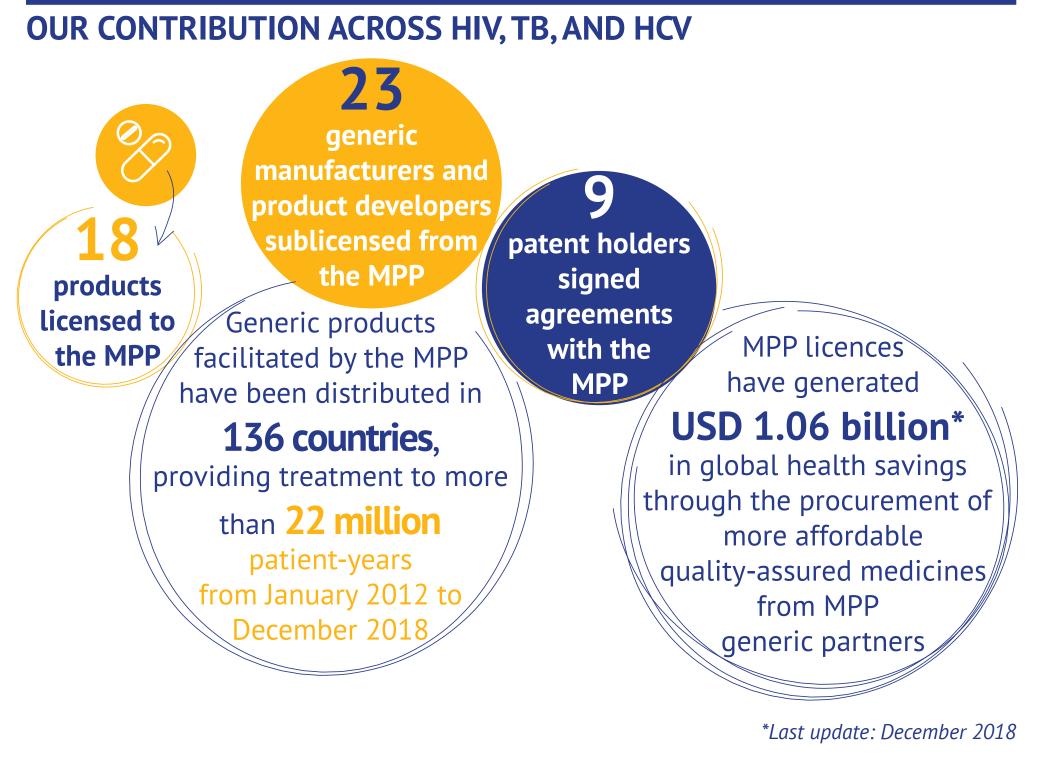
The Medicines Patient Pool (MPP) is a United Nations-backed public health organisation working to improve access to affordable quality-assured medicines in developing countries through public health-oriented licences and patent pooling. It was founded by Unitaid in 2010 to contribute to the HIV response, with its mandate being expanded twice: to the hepatitis C virus (HCV) and tuberculosis in 2015, and to other patented essential medicines in 2018.

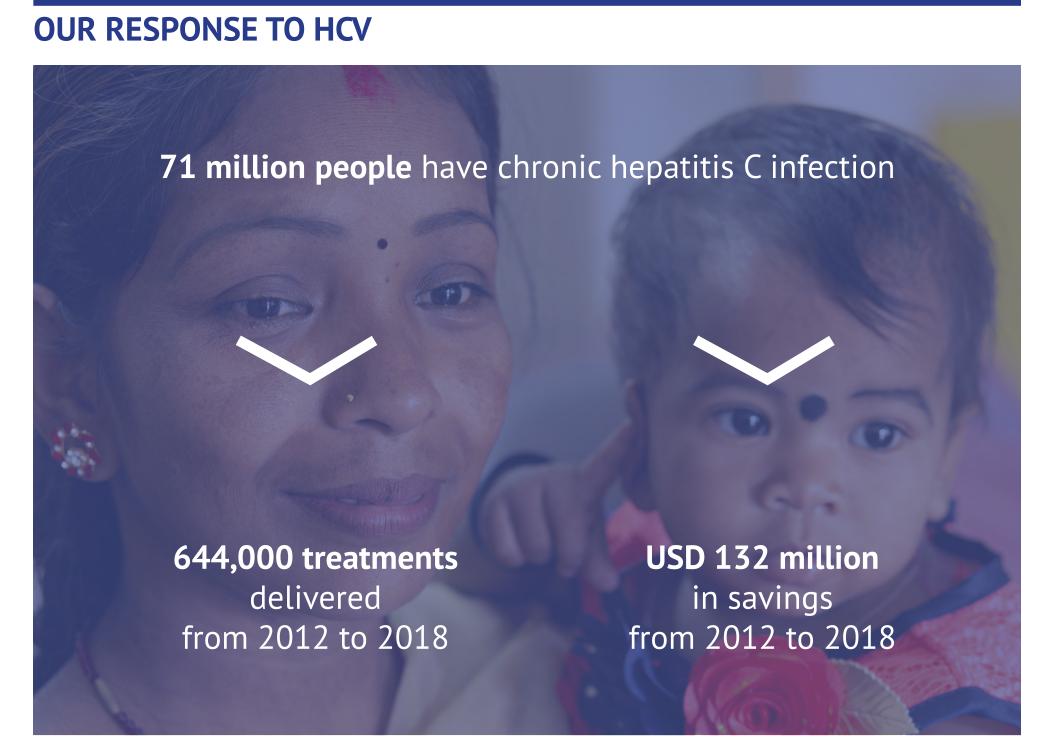
The MPP is the only access-oriented licensing and patent pooling mechanism in the public health space. Its model is based on collaborative access-oriented agreements that ensure patented treatments of high clinical relevance rapidly become available in low- and middle-income countries (LMICs), and enable the development of fixed-dose combinations and adapted formulations for children. Through this mechanism, up to 131 countries can now access affordable quality-assured generic versions of these medicines. Currently, the MPP holds licences on 18 products with nine patent holders enabling 23 partners to develop, register, manufacture and supply WHO-recommended products.

To date, MPP generic partners have delivered 22 million patient-years of treatment, resulting in USD 1.06 billion in global health savings through the procurement of more affordable quality-assured medicines from MPP generic partners.

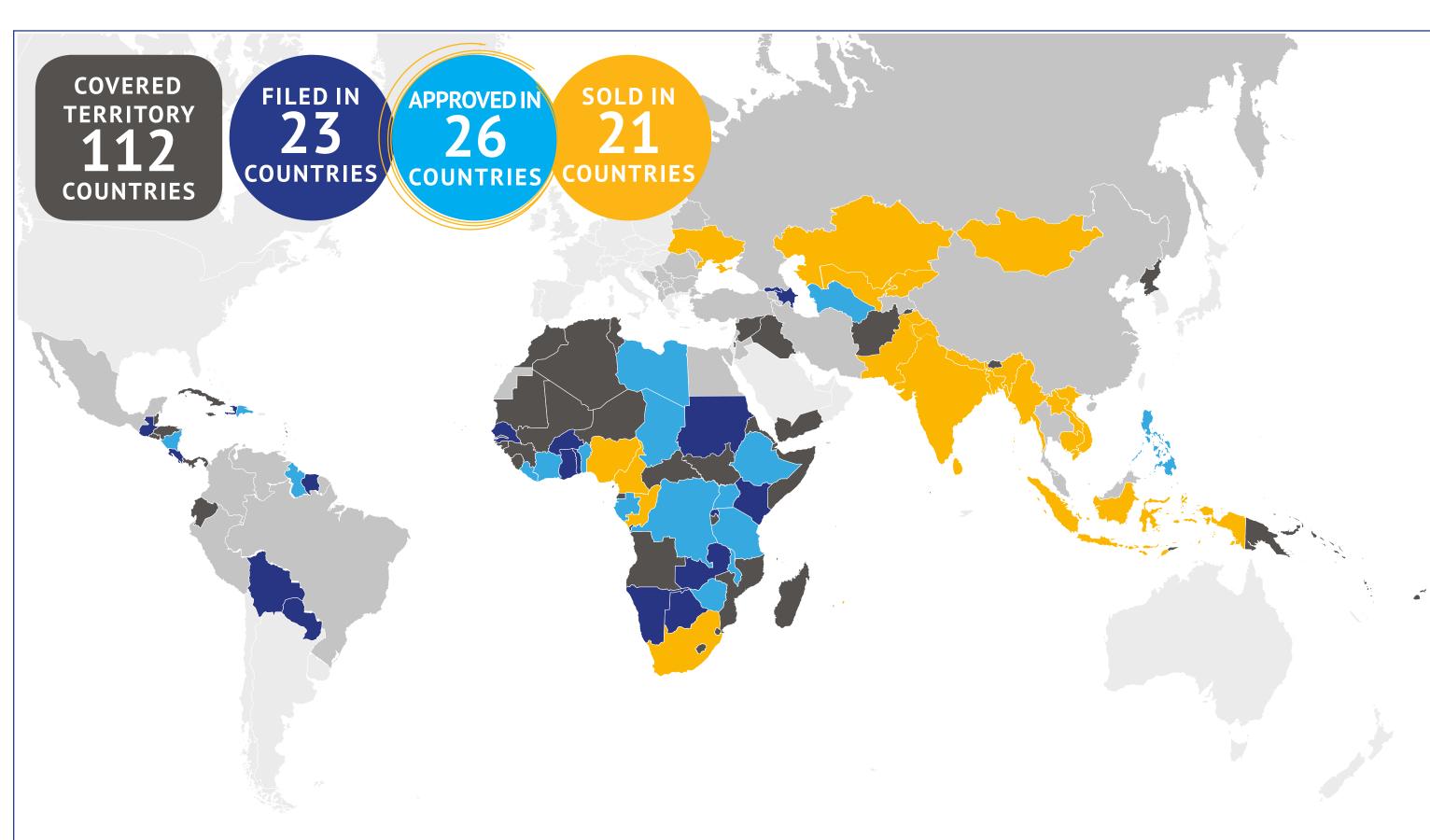
The MPP contributes to the HCV elimination efforts by licensing new and pipeline pan-genotypic direct-acting antivirals (DAAs). The MPP signed its first licence agreement for a HCV treatment in 2015 for daclatasvir (DAC), part of the WHO-recommended preferred first-line regimen with sofosbuvir (SOF). Another licence was signed in 2017 for the investigational DAA ravidasvir (RAV). In November 2018, the MPP signed a licence for glecaprevir/pibrentasvir (G/P), a WHO-recommended pan-genotypic treatment for HCV. As of now, the MPP works with ten generic partners to accelerate the development and distribution in countries with high HCV burden of recommended treatments that can cure the disease through a short course of oral therapy.







PRODUCTS DEVELOPED THROUGH MPP LICENCES



DACLATASVIR 30MG AND 60MG

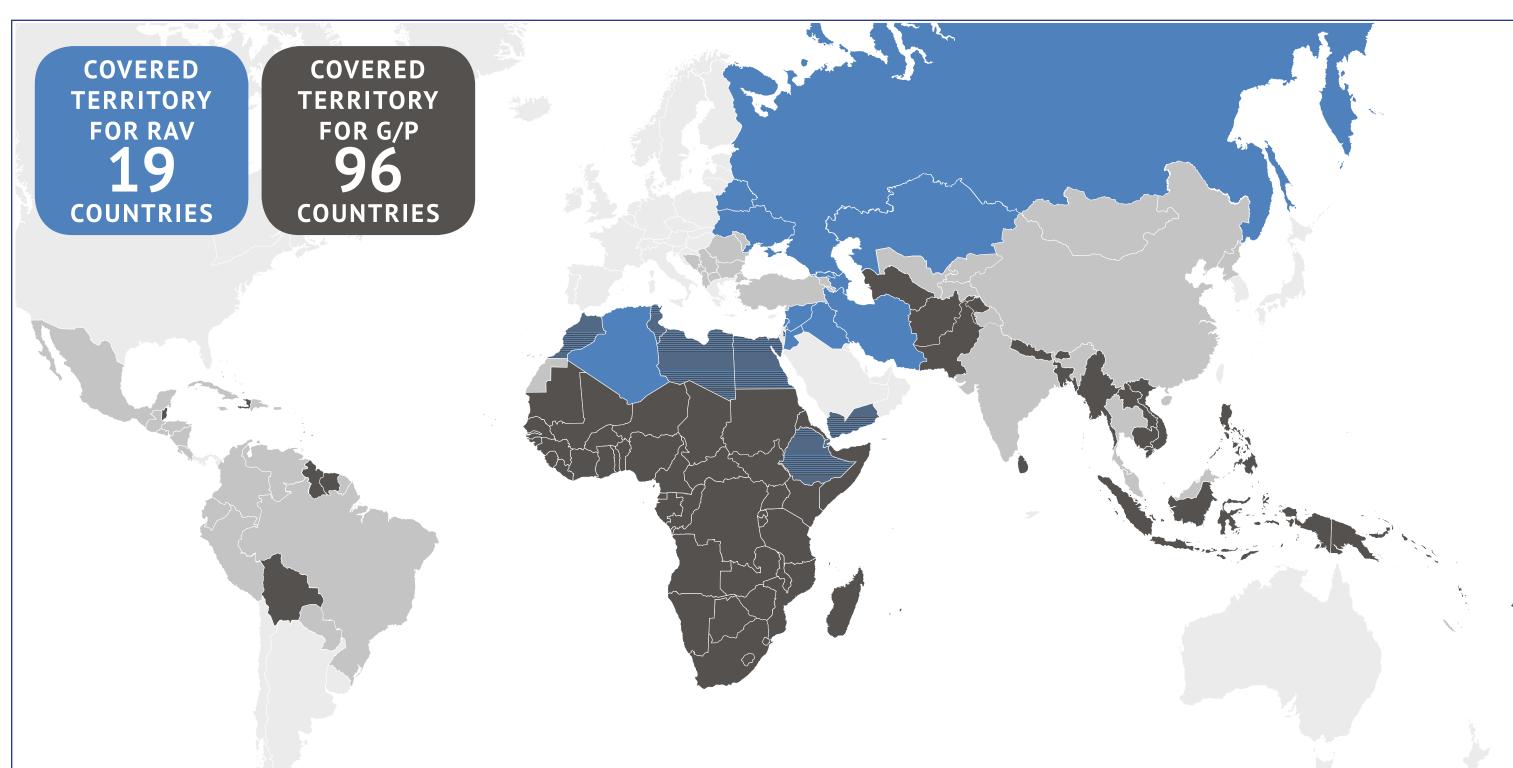
As of March 2019, five companies were developing the two products, of which Cipla and Mylan received approval from the Expert Review Panel (ERP) led by WHO. Mylan also received WHO Prequalification (WHO-PQ). The territory covered by the MPP licence is 112 countries. Generic DAC is approved in 26 countries, sold in 21 countries and filed in another 23 countries.

COVERED TERRITORY 16 COUNTRIES COUNTRIES COUNTRIES COUNTRIES Will be disclosed when more than one approval from stringent regulatory authorities is granted

DACLATASVIR + SOFOSBUVIR (DAC + SOF)

As of March 2019, three 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 for DAC is 112 countries (the bilateral licence for SOF by Gilead Sciences covers 107 countries). Generic DAC + SOF is approved in six countries, sold in two and filed in another 16 countries.

PRODUCTS UNDER DEVELOPMENT



RAVIDASVIR (RAV) AND GLECAPREVIR/PIBRENTASVIR (G/P)

In 2017, the MPP and Pharco Pharmaceuticals signed a licence and technology transfer agreement for RAV, an investigational DAA with the potential of working across all six major hepatitis C genotypes. This licence complements a bilateral licence between Presidio, the original developer of RAV, and the Drugs for Neglected Diseases *initiative* (DND*i*). In 2018, the MPP signed a royalty-free licence agreement with AbbVie for G/P – a WHO-recommended treatment for people living with HCV. The licence enables quality-assured manufacturers to develop and sell generic medicines containing G/P in 96 LMICs.

FIND OUT MORE

Stakeholders interested in learning more on the patent and licence landscape in this area (and other essential medicines) are invited to consult our online Medicines Patents and Licenses Database MedsPaL. An open access/ free database providing information on the patent and licensing status of patented medicines on the WHO Essential



Medicines List (EML) in LMICs, MedsPaL includes patent and licensing data covering 110 medicines (180+ formulations) in more than 130 LMICs.

www.medspal.org

Stakeholders interested in exploring access for countries where these medicines are not yet registered are welcome to reach out to the MPP team as we can provide support.

CONTACT INFORMATION

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We would like to thank our founder Unitaid which serves as sole funder for the MPP's activities in HIV, hepatitis C and tuberculosis. The MPP is now expanding its activities to cover all essential medicines, which requires engagement with many new stakeholders, including potential funders. We also thank our partners: civil society, governments, international organisations, patient groups, industry and other stakeholders.



High-income countries • Low- and middle-income countries

REFERENCES

Medicines Patent Pool <u>2018 Annual Report</u>
MPP Website: <u>www.medicinespatentpool.org</u>
Update on Progress of MPP Sublicensees: <u>https://bit.ly/2NDyINd</u>

MedsPaL: www.medspal.org
World Health Organization, Key Facts: https://bit.ly/2XTMMee
Daclatasvir (DAC):
www.medicinespatentpool.org/licence-post/daclatasvir-dcv/

Ravidasvir (RAV):

<u>www.medicinespatentpool.org/licence-post/ravidasvir/</u>

Glecaprevir/pibrentasvir (G/P):

<u>www.medicinespatentpool.org/licence-post/glecaprevirpibrentasvir-gp/</u>