# Disease Burden of HIV/AIDS, TB, Hepatitis C and COVID-19 in South and South-East Asia

## Patent Protection and Access to Medicines and Vaccines

## Introduction

Countries in the South and South East Asia region constitute one of the most populous regions of the world. The countries in the region are confronted with the double burden of disease - rising incidence of non-communicable diseases such as cancer, cardiovascular diseases, diabetes, etc. as well as communicable infectious diseases such as HIV/AIDS, tuberculosis, and hepatitis C. The region has the highest share of the global burden of tuberculosis which is a silent epidemic that is ravaging through the countries in the region, even while a rapid surge of COVID-19 has severely impacted these countries. The region also has a high burden of hepatitis C and a significant burden of HIV/AIDS. Patients with HIV/AIDS are at increased risk of co-infections of tuberculosis and hepatitis C. Thus, a large of patients in the countries from the region face the burden or threat of confronting multiple disease burdens simultaneously. Such patients are also at higher risk of suffering from acute COVID-19 infections.

This disease burden can be addressed adequate and affordable access to treatments (including vaccines in the case of COVID-19). In this context, the existence of patent monopolies on some of the critical drugs or vaccines needed for addressing this disease burden can present a significant challenge to the ability of these countries to address the public health need. The appropriate and fullest use of TRIPS flexibilities in relation to such patents can therefore play a critical role in facilitating better access to such treatments.

| Disease | Patients | Treatment | Patented Drugs |
|---|---|---|---|
| HIV/AIDS | About 6.7 million (2019) | 60-65 per cent patients with access to antiretroviral treatment | Dolutegravir, Lopinavir/Ritonavir combination, Darunavir/Ritonavir combination, Zidovudine oral solution (for infants and children), Nevirapine oral solutions (for infants |

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|---|---|---|---|
| | | | and children), Raltegravir (oral suspension for infants and children) |
| Tuberculosis | More than 587 million | About 40 per cent of patients with drug resistant TB with access to treatment | Bedaquiline, Delamanid, Pretomanid, Rifapentine/Isoniazid combination |
| Hepatitis C | More than 10 million | Globally about 40 per cent patients lack access to treatment | Sofusbuvir |

## HIV/AIDS

In 2018, out of the 37.9 people living with HIV globally, 3.8 million were living in 11 countries of the South-East Asia Region of WHO, and 1.9 million patients were living in the countries of the Western Pacific Region of the WHO (including Malaysia, Myanmar, China). According to UNAIDS, HIV infections in Asia and the Pacific have declined slightly, with reductions in Cambodia, Myanmar, Thailand and Viet Nam offset by sharp increases in Pakistan and the Philippines. Key populations and their partners accounted for an estimated 98% of new HIV infections, and more than one quarter of new HIV infections were among young people (aged 15 to 24 years). According to the WHO global progress report 2020, HIV treatment coverage increased from 37% in 2015 to 61% in 2020 in the South East Asia region, but the region is off-track for achieving the 2020 targes, which includes ensuring 90 per cent of patients with HIV receiving antiretroviral treatment.

While the number of patients with HIV/AIDS has reduced substantially globally and in the region it is still too high, and mortality is decreasing too slowly. The global target of less than 500000 deaths and ensuring access to treatment for 90 per cent of patients in all countries by 2020 has been missed in most countries. While increased generic availability of first-line antiretroviral treatments for HIV/AIDS facilitated by the absence of patents on related drugs has contributed to significant reduction in the burden of HIV/AIDS, (for example, for Abacavir, Atazanavir, Lopinavir and Ritonavir), but secondary patents over such drugs have been claimed in countries such as China and India (such as combinations, second uses, other forms, etc.) have been filed, as well as for new second or third-line treatments that address viral resistance to the first line treatments (e.g. Cabotegravir, Darunavir, Dolutegravir) and candidate drugs. Therefore, in spite

of the generic availability of first line drugs, ARV treatment (ART) coverage remains too low. By the end of 2019, about 60-65 per cent patients had access to treatments, leaving a deadly gap of more than 2.3 million people without access to treatment in South East Asia and the Western Pacific Region. ARV treatment (ART) coverage remains too low. The access gap is even wider for children living with HIV/AIDS. Globally, only 53% of the 1.8 million children living with HIV (0-14 years old) had access to ART in 2019.

THE CASE OF DOLUTEGRAVIR

Dolutegravir (DTG), an integrase inhibitor produced by ViiV (a joint venture by Pfizer, GlaxoSmithKline and Shionogi), is the backbone for first-line ARV treatment recommended by the World Health Organization (WHO) for infants, children, adolescents and adults living with HIV. The only formulation currently available commercially for children under 20 kg is Viiv's dispersible tablet priced at $33-50 per bottle of 60 tablets. This equates to $806- 1,226 per year for a child weighing 10 kg, a price far out of reach for low- and middle-income countries (LMICs). Seven years after DTG was first approved by the US Food and Drug Administration (FDA) for adults,7 most children still do not have access to this drug recommended for first-line treatment by WHO since 2018. Though generic formulations can be made available at a fraction of the price, the existence of patents in key manufacturing countries can create impediments to the availability of the generic drugs, until their expiry in 2026 (about 359 patents in total have been filed or granted on dolutegravir, including the compound, its salt forms, formulations, or combinations with other ARV drugs, etc., in India, Indonesia, Malaysia, Pakistan, the Philippines, Thailand and Viet Nam). Currently, access to the drug is dependent on the terms of a licensing agreement between the patentee (ViiV) and the Medicines Patent Pool, which has excluded some countries (e.g., China) from the scope of the license or limited the access to paediatric formulations, excluding dosage formulations for adults (e.g., Malaysia).

Source: MSF Access Campaign, https://msfaccess.org/untangling-web-hiv-medicine-pricing-access-issues-2020

## Tuberculosis

The WHO South-East Asia (SEA) Region accounts for 44% of the global burden of TB incidence. Of about 1.7 billion patients infected with TB globally, about 587 million infected patients are from this region. In 2019, an estimated 4.3 million people fell ill with TB and estimated 632 000 died because of the disease which is more than half of global TB deaths. Rifampicin-resistant (RR) and multi-drug-resistant TB (MDR-TB) cases accounting for more than 35% of global burden

appeared in the Region in 2019. About 60% of the patients with RR and MDR TB do not have access to the safe and efficacious treatments that are available today. Six out of the 30 high TB (and MDR-TB) burden countries are in the SEA Region: Bangladesh, Democratic People's Republic of Korea, India, Indonesia, Myanmar and Thailand.

Increasing cases of drug resistant (DR) TB is a serious public health challenge for the countries in South and South East Asia. Accelerating treatment and prevention of DR TB will require increased access to critical TB medicines such as bedaquiline, delamanid and pretomanid. Bedaquiline and delamanid are part of the WHO recommended treatment regimens that are safer, more effective and easier to take than past regimens. However, high prices and patents on these medicines continue to be major hurdles to accessing these life-saving treatments. Bedaquiline which is priced at US$ 1.50 per day for some countries, but according Medecins Sans Frontieres, the price could be as low as US$ 0.25 per day as substantial public funding has supported the research and development of this drug. Globally, only 11% of the patients needing the drug have been able to access it. Delamanid is one of the most expensive TB medicines in the world priced at about US$1700 for a six month course.

These drugs are under patent protection in several countries. Janssen, a subsidiary of Johnson & Johnson, has obtained or filed for multiple patents on the bedaquiline. While the patent on the primary base compound will expire in 2023, the effective term of the patent monopoly could be longer due to several secondary patent claims that have been filed, including on salt forms, different indications or uses of the drug such as specific use of the drug for treatment of MDR-TB, paediatric formulations, long-acting injecting formulations, etc. Some of these patents have been opposed by patients groups in a number of countries, including India and Thailand. Similarly, patent claims over delamanid covering the basic compound, the API process and intermediates, formulations and combinations with other TB drugs have been filed by Otsuka in several countries. The TB Alliance has also filed patent applications on formulations ofanother drug for the treatment of TB, pretomanid, as part of a combination with other TB drugs, in high burden countries including India. Future patent claims could also arise on a number of other candidate drugs that are currently in the pipeline. In addition, secondary patents have been claimed or granted on fixed dose combinations of two drugs that are off-patent and recommended by WHO for TB preventive treatment – rifapentine and isoniazid.

## Hepatitis C

As noted by the WHO, "Viral hepatitis is the seventh leading cause of mortality worldwide and is the only communicable disease where mortality is increasing.

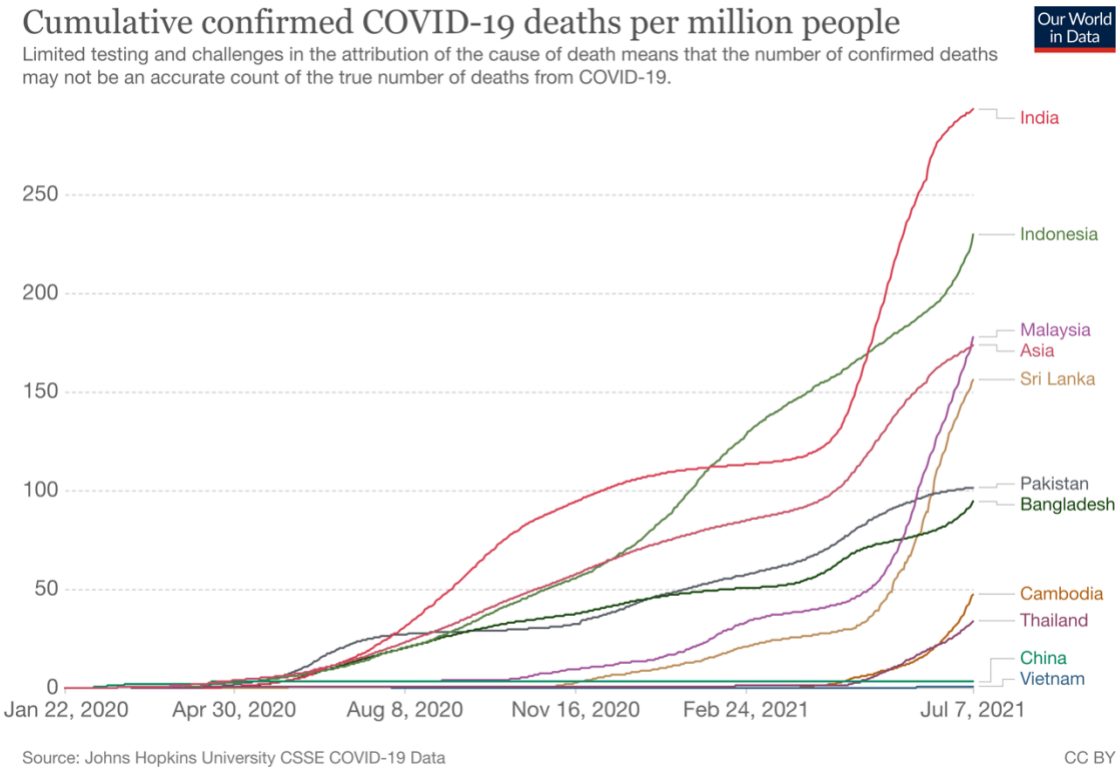
Viral hepatitis cause at least as many, if not more, deaths annually than TB, AIDS or malaria combined." It is estimated that 58 million people have chronic hepatitis C virus infection, with about 1.5 million new infections occurring per year. In 2019, the WHO estimated that 290.000 people died from hepatitis C In the Eastern Mediterranean region (including Pakistan, with estimation of up to 8.64% of the population), around 12 million people have Hepatitis C; in Southeast Asia, there around 10 million people living with hepatitis C. China, India and Pakistan are among the highest hepatitis C burden countries in the world.

Hepatitis C was until recently a disease without any cure, and there are not available vaccines. The WHO recommends the use of direct-acting antivirals, which may be successful in up to 95% of the cases. A new drug, sofosbuvir, offers much more effective treatment options for patients, but the drug is under patent protection granted to the multinational company Gilead Pharmaceuticals, and is so highly priced that it is unaffordable for public health programmes even in very rich countries. The cost of the 12-week treatment was priced at up to US$ 80.000, while generic versions could cost as little as US$ 2.000 USD (in Egypt). In 2017, Malaysia issued a compulsory license for sofosbuvir in 2017, which enabled drastic reductions in prices and massively enhancing access to Hepatitis C in the country. Therefore, generic competition has been a key element in the fight against the disease in developing countries.

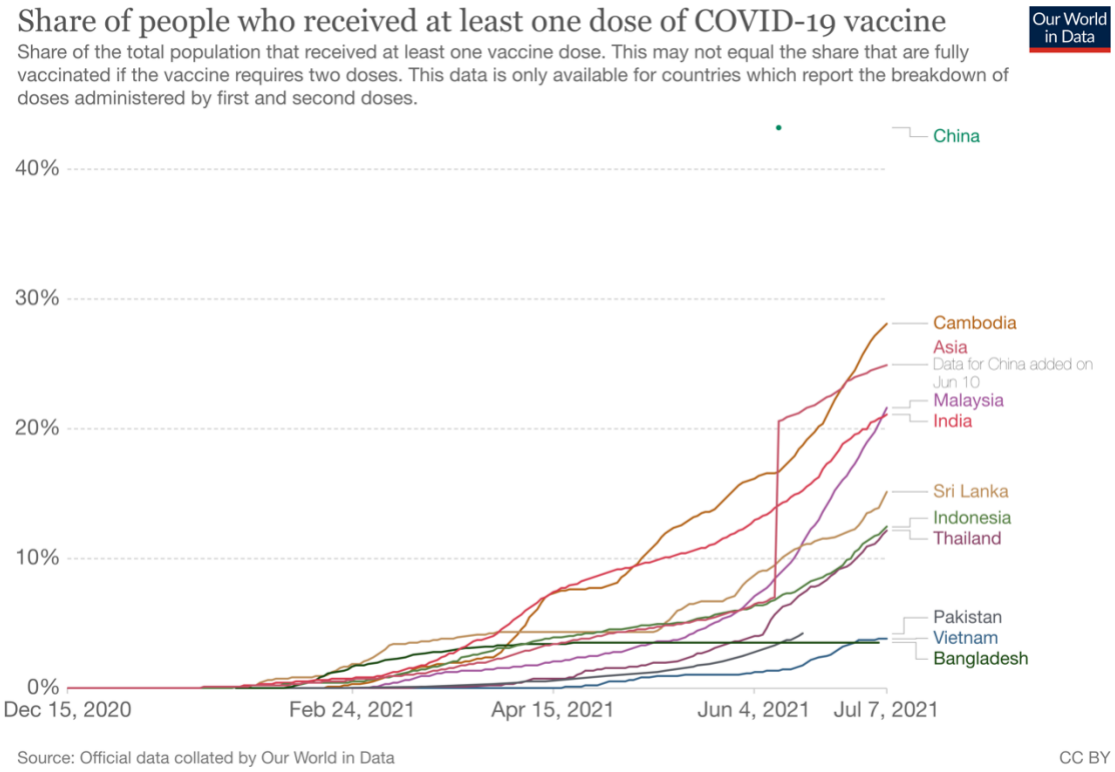
The existing drugs for Hepatitis C are heavily patented. Sofosbuvir and combinations such as Sofosbuvir/Dataclasvir and Sofosbuvir/Velpatasvir have various granted or filed patents in China, Indonesia, Malaysia, and Viet Nam. Patents include the compound, the combination, manufacturing processes, active metabolite, crystalline forms, among others. In India, most of granted patents have been opposed, but some are valid (e.g. IN4972/KOLNP/2011 valid until 20 May 2030). In Thailand, patent applications have been opposed and pending applications have not been granted patents so far.

## COVID-19

The Covid-19 pandemic has led the largest health, economic and social crisis in at least a century. With over 4.2 million confirmed deaths and the long-lasting effects of "Long Covid", healthcare systems have been overwhelmed around the world. Asian countries performed quite differently in the management of the pandemic but no country was exempt from the consequences of the pandemic. As of July 2021, even the very successful cases of Viet Nam, Thailand, and China are struggling to cope with and eradicate infections due to the Delta variant.




The global unequal allocation of Covid-19 vaccines, with less than 1% of vaccines inoculated in low-income countries has highlighted the limitations of the existing mechanisms for equitable distribution and the necessity to overcome all possible barriers to ensure access to different vaccines. While high-income countries now face rising Covid-19 cases with reduced burden to the health system, translated in overall lower numbers of hospitalizations and deaths, the recent waves in Asian countries such as India, Malaysia, Myanmar and Indonesia reflect a very distinct scenario, where the number of vaccinated persons is overall extremely low. Among Asian developing countries, Bhutan and Mongolia stand out as exceptions which nonetheless prove the overall global inequity problem, as well as China, which is the single largest manufacturer and exporter of Covid-19 vaccines to other countries as well.

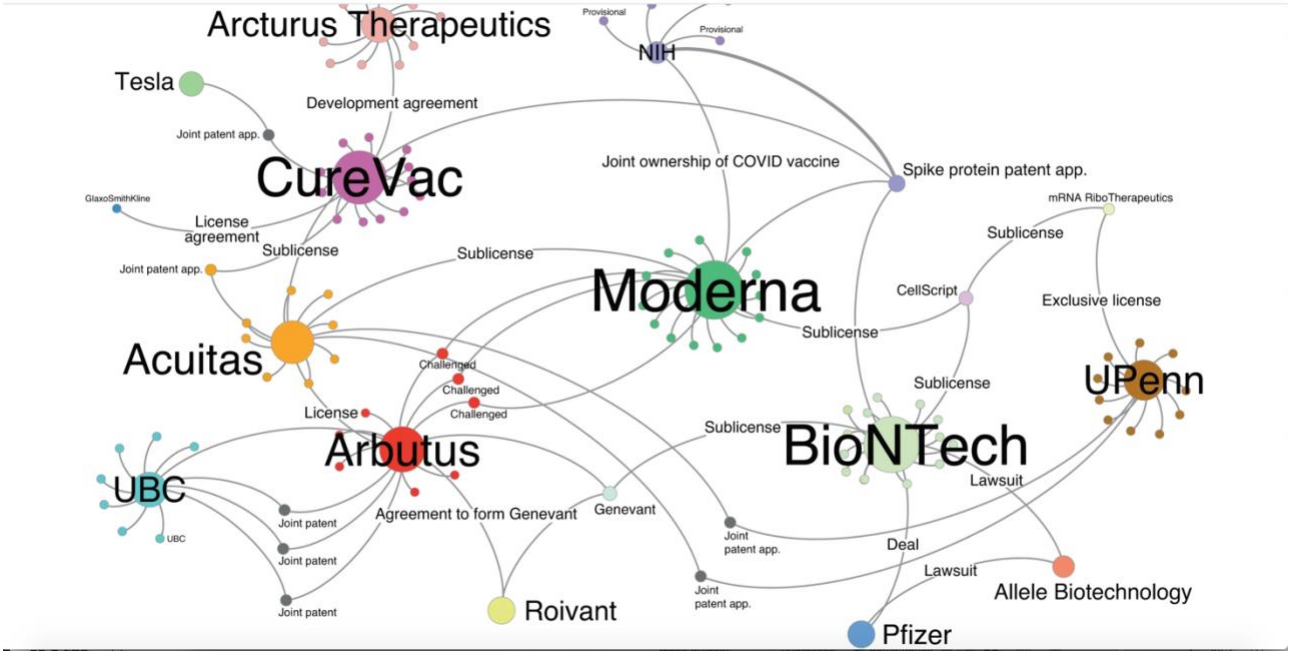



One key limitation is the existence of various forms of IPRs in Covid-19 vaccines, particularly patents and trade secrets. It adds to the problem of insufficient or inexistent manufacturing capacity in many countries, but in reality the existing capacity is currently underutilized in multiple countries, including Bangladesh, India, Thailand, Malaysia, and Indonesia, at least. Although some voluntary agreements between companies have been undertaken with companies in India and Thailand, the limitations are evident. Even if companies would be able to reverse engineer (a lawful practice), they would be infringing patents on Covid-19 vaccines. Because of the period of confidentiality pursuant to the filing of a patent, there is not yet a clear identification of the exact applications for each vaccine in each country. China has reportedly already granted several patents for its national Sinovac, Sinopharm and Cansino vaccines[1], and has reportedly filed other broad patent filings which may impact other vaccines as well. Regarding mRNA vaccines such as Pfizer/BioNTech and Moderna, there is clarity with respect to the existence of various patent barriers, as highlighted by the figure below.

*For more information, please refer to the specific Covid-19 material for the course.*

[1] For example, see: https://www.natlawreview.com/article/china-s-first-covid-19-virus-vaccine-patent-granted-to-cansino-bio

**Patent network analysis of mRNA-based vaccine candidates for COVID-19**




Source: GAVIRIA, Mario; KILIC, Burcu. **A network analysis of COVID-19 mRNA vaccine patents.** *Nature Biotechnology* **39,** 546–548, 2021. Available at: https://www.nature.com/articles/s41587-021-00912-9

In the field of treatments, the once potential candidate **Remdesivir** has patents granted in China (all granted), India (one opposed), Indonesia, Malaysia and Viet Nam, as well as filings in Thailand. **Tociluzumab,** approved by the WHO as one treatment for Covid-19, has numerous granted patents in China, and some in India, Indonesia, Malaysia, Viet Nam and Thailand. Patent holders Roche and Chugai has nonetheless announced that they would not assert patents on Tociluzumab during the Covid-19 pandemic, although it is unclear up until when and what the scope of this non-enforcement would be. Various other potential treatments whose clinical trials have not been concluded have similarly has patents filed and granted in the all such countries, including AT-527, Dapagliflozin, Darunavir/Cobicistat, Favipiravir, and Tuxolitinib.

Barriers related to IPRs are not exclusively those related to vaccines and treatment medicines, but also testing kits, diagnostics, personal protective equipment (PPEs), and various other medical devices and equipment, including oxygen tanks. Many of these are protected by a bundle of patents, trademarks, industrial designs (or design patents), as well as trade secrets. There is a difficulty for countries to assess exactly what IPRs might be covering each of them, and this may also impede the development of generic alternatives. For example, in Brazil, a low-cost open source (i.e., licensed at no cost without IP protection) respirator developed by the

University of São Paulo struggled with both regulatory issues for its approval at the national health agency and the likelihood of infringing existing patents for some of its components. Ultimately, this elevated legal risk impeded its wide utilization during the most pressing moments of the pandemic, including during the oxygen shortages in January 2021 in the city of Manaus.

## ANNEX

### Patents on TB Drugs

| Jurisdiction | Product Name(s) | Patent Description | Patent Status | Patent Application Number | Expected Expiry Date (dd/mm/yyyy) | Last Updated On (dd/mm/yyyy) |
|---|---|---|---|---|---|---|
| **India** | Bedaquiline 100 mg | Bedaquiline compounds | Granted | IN220/DELNP/2005 | 18/07/2023 | 29/10/2020 |
| **India** | Bedaquiline 100 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Granted | IN6315/DELNP/2006 | 24/05/2025 | 28/10/2020 |
| **India** | Bedaquiline 100 mg | Bedaquiline to treat latent TB | Rejected | IN5213/DELNP/2007 | | 28/03/2017 |
| **India** | Bedaquiline 100 mg | Bedaquiline process | Granted | IN9746/DELNP/200 | 22/05/2026 | 28/10/2020 |
| **India** | Bedaquiline 100 mg | Bedaquiline fumarate salt | Filed (opposed) | IN1220/MUMNP/2009 | 03/12/2027 | 08/06/2021 |
| **India** | Bedaquiline 20 mg | Bedaquiline compounds | Granted | IN220/DELNP/2005 | 18/07/2023 | 29/10/2020 |
| **India** | Bedaquiline 20 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Granted | IN6315/DELNP/2006 | 24/05/2025 | 28/10/2020 |
| **India** | Bedaquiline 20 mg | Bedaquiline to treat latent TB | Rejected | IN5213/DELNP/2007 | | 28/03/2017 |
| **India** | Bedaquiline 20 mg | Bedaquiline process | Granted | IN9746/DELNP/200 | 22/05/2026 | 28/10/2020 |
| **India** | Bedaquiline 20 mg | Bedaquiline fumarate salt | Filed (opposed) | IN1220/MUMNP/2009 | 03/12/2027 | 08/06/2021 |
| **India** | Bedaquiline 20 mg | Bedaquiline dispersible tablet formulations | Withdrawn | IN264/MUM/2015 | | 02/07/2020 |
| **India** | Bedaquiline 20 mg | Bedaquiline dispersible tablet formulations | Filed (opposed) | IN201727030045 | 26/01/2036 | 11/06/2021 |
| **India** | Delamanid 50 mg | Delamanid compounds | Granted | IN600/KOLNP/2005 | 10/10/2023 | 28/10/2020 |
| **India** | Delamanid 50 mg | Delamanid compounds | Rejected | IN1647/KOLNP/2007 | | 14/11/2019 |
| **India** | Delamanid 50 mg | Delamanid compounds to treat TB | Withdrawn | IN824/KOLNP/2006 | | 17/10/2019 |
| **India** | Delamanid 50 mg | Delamanid compositions with selected cellulose compounds | Granted | IN9790/DELNP/2007 | 19/07/2026 | 28/10/2020 |
| **India** | Delamanid 50 mg | Delamanid combined with other TB drugs | Withdrawn | IN1255/KOLNP/2008 | | 29/10/2020 |
| **India** | Isoniazid/Rifapentine | Isoniazid/Rifapentine coated tablet compositions | Withdrawn | IN3341/CHE/2013 | | 23/05/2019 |
| **India** | Isoniazid/Rifapentine | Isoniazid/Rifapentine coated tablet compositions | Withdrawn | IN201637002757 | | 01/04/2020 |

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| **India** | Isoniazid/Rifapentine | Isoniazid/Rifapentine dispersible tablet compositions | Withdrawn | IN201637002758 | | 01/04/2020 |
| **India** | Isoniazid/Rifapentine | Rifapentine compound & process | Not Filed | | | |
| **India** | Isoniazid/Rifapentine | Isoniazid use in TB | Not Filed | | | |
| **Indonesia** | Bedaquiline 100 mg | Bedaquiline compounds | Granted | IDW00200500183 | 18/07/2023 | 16/06/2021 |
| **Indonesia** | Bedaquiline 100 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Granted | IDW00200603351 | 24/05/2025 | 16/06/2021 |
| **Indonesia** | Bedaquiline 100 mg | Bedaquiline to treat latent TB | Granted | IDW00200702008 | 08/12/2025 | 16/06/2021 |
| **Indonesia** | Bedaquiline 100 mg | Bedaquiline fumarate salt | Granted | IDW00200901493 | 03/12/2027 | 16/06/2021 |
| **Indonesia** | Bedaquiline 20 mg | Bedaquiline compounds | Granted | IDW00200500183 | 18/07/2023 | 16/06/2021 |
| **Indonesia** | Bedaquiline 20 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Granted | IDW00200603351 | 24/05/2025 | 16/06/2021 |
| **Indonesia** | Bedaquiline 20 mg | Bedaquiline to treat latent TB | Granted | IDW00200702008 | 08/12/2025 | 16/06/2021 |
| **Indonesia** | Bedaquiline 20 mg | Bedaquiline fumarate salt | Granted | IDW00200901493 | 03/12/2027 | 16/06/2021 |
| **Indonesia** | Bedaquiline 20 mg | Bedaquiline dispersible tablet formulations | Filed | ID201704901 | 26/01/2036 | 14/06/2021 |
| **Indonesia** | Delamanid 50 mg | Delamanid compositions with selected cellulose compounds | Granted | IDW00200800233 | 19/07/2026 | 16/06/2021 |
| **Indonesia** | Delamanid 50 mg | Delamanid combined with other TB drugs | Revoked | ID00200801089 | | 15/11/2019 |
| **Indonesia** | Isoniazid/Rifapentine | Isoniazid/Rifapentine coated tablet compositions | Withdrawn | IDP00201601205 | | 17/11/2019 |
| **Indonesia** | Isoniazid/Rifapentine | Isoniazid/Rifapentine dispersible tablet compositions | Withdrawn | IDP00201601207 | | 17/11/2019 |
| **Indonesia** | Isoniazid/Rifapentine | Rifapentine compound & process | Not Filed | | | |
| **Indonesia** | Isoniazid/Rifapentine | Isoniazid use in TB | Not Filed | | | |
| **Malaysia** | Bedaquiline 100 mg | Bedaquiline compounds | Granted | MYPI20032793 | 24/07/2023 | 05/11/2020 |
| **Malaysia** | Bedaquiline 100 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Granted | MYPI20052432 | 27/05/2025 | 05/11/2020 |
| **Malaysia** | Bedaquiline 100 mg | Bedaquiline to treat latent TB | Granted | MYPI20055732 | 07/12/2025 | 05/11/2020 |
| **Malaysia** | Bedaquiline 100 mg | Bedaquiline fumarate salt | Granted | MYPI20092284 | 03/12/2027 | 06/11/2020 |

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| **Malaysia** | Bedaquiline 20 mg | Bedaquiline compounds | Granted | MYPI20032793 | 24/07/2023 | 05/11/2020 |
| **Malaysia** | Bedaquiline 20 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Granted | MYPI20052432 | 27/05/2025 | 05/11/2020 |
| **Malaysia** | Bedaquiline 20 mg | Bedaquiline to treat latent TB | Granted | MYPI20055732 | 07/12/2025 | 05/11/2020 |
| **Malaysia** | Bedaquiline 20 mg | Bedaquiline fumarate salt | Granted | MYPI20092284 | 03/12/2027 | 06/11/2020 |
| **Malaysia** | Bedaquiline 20 mg | Bedaquiline dispersible tablet formulations | Not Filed | | | |
| **Malaysia** | Delamanid 50 mg | Delamanid compounds | Granted | MYPI20033866 | 10/10/2023 | 05/11/2020 |
| **Malaysia** | Delamanid 50 mg | Delamanid compounds to treat TB | Withdrawn | MYPI20044505 | | 03/12/2019 |
| **Malaysia** | Delamanid 50 mg | Delamanid compositions with selected cellulose compounds | Granted | MYPI20063579 | 26/07/2026 | 06/11/2020 |
| **Malaysia** | Delamanid 50 mg | Delamanid combined with other TB drugs | Withdrawn | MYPI20080873 | | 03/12/2019 |
| **Malaysia** | Delamanid 50 mg | Delamanid intermediate compounds | Withdrawn | MYPI2012003014 | | 03/12/2019 |
| **Malaysia** | Isoniazid/Rifapentine | Isoniazid/Rifapentine coated tablet compositions | Rejected | MYPI2015704801 | | 14/10/2020 |
| **Malaysia** | Isoniazid/Rifapentine | Isoniazid/Rifapentine dispersible tablet compositions | Withdrawn | MYPI2015704792 | | 14/10/2020 |
| **Malaysia** | Isoniazid/Rifapentine | Rifapentine compound & process | Not Filed | | | |
| **Malaysia** | Isoniazid/Rifapentine | Isoniazid use in TB | Not Filed | | | |
| **Pakistan** | Bedaquiline 100 mg | Bedaquiline compounds | Granted | PK20061114 | 23/07/2023 | 06/02/2020 |
| **Pakistan** | Bedaquiline 100 mg | Bedaquiline compounds | Granted | PK20061113 | 23/07/2023 | 06/02/2020 |
| **Pakistan** | Bedaquiline 100 mg | Bedaquiline compounds | Granted | PK20030640 | 23/07/2023 | 22/10/2018 |
| **Pakistan** | Bedaquiline 100 mg | Bedaquiline to treat latent TB | Granted | PK735/2011 | 24/12/2024 | 28/07/2020 |
| **Pakistan** | Bedaquiline 100 mg | Bedaquiline to treat latent TB | Granted | PK1163/2005 | 24/12/2024 | 28/07/2020 |
| **Pakistan** | Bedaquiline 100 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Filed | PK20050467 | 25/05/2025 | 01/10/2016 |
| **Pakistan** | Bedaquiline 100 mg | Bedaquiline fumarate salt | Filed | PK1403/2007 | 03/12/2027 | 27/09/2019 |
| **Pakistan** | Bedaquiline 20 mg | Bedaquiline compounds | Granted | PK20061114 | 23/07/2023 | 06/02/2020 |
| **Pakistan** | Bedaquiline 20 mg | Bedaquiline compounds | Granted | PK20061113 | 23/07/2023 | 06/02/2020 |
| **Pakistan** | Bedaquiline 20 mg | Bedaquiline compounds | Granted | PK20030640 | 23/07/2023 | 22/10/2018 |

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| **Pakistan** | Bedaquiline 20 mg | Bedaquiline to treat latent TB | Granted | PK735/2011 | 24/12/2024 | 28/07/2020 |
| **Pakistan** | Bedaquiline 20 mg | Bedaquiline to treat latent TB | Granted | PK1163/2005 | 24/12/2024 | 28/07/2020 |
| **Pakistan** | Bedaquiline 20 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Filed | PK20050467 | 25/05/2025 | 01/10/2016 |
| **Pakistan** | Bedaquiline 20 mg | Bedaquiline fumarate salt | Filed | PK1403/2007 | 03/12/2027 | 27/09/2019 |
| **Pakistan** | Bedaquiline 20 mg | Bedaquiline dispersible tablet formulations | Not Filed | | | |
| **Pakistan** | Delamanid 50 mg | Delamanid compositions with selected cellulose compounds | Filed | PK20060826 | 20/07/2026 | 03/10/2016 |
| **Pakistan** | Delamanid 50 mg | Delamanid combined with other TB drugs | Filed | PK200601314 | 03/10/2026 | 03/10/2016 |
| **Pakistan** | Isoniazid/Rifapentine | Rifapentine compound & process | Not Filed | | | |
| **Pakistan** | Isoniazid/Rifapentine | Isoniazid use in TB | Not Filed | | | |
| **Philippines** | Bedaquiline 100 mg | Bedaquiline compounds | Granted | PH12010502363 | 18/07/2023 | 18/11/2020 |
| **Philippines** | Bedaquiline 100 mg | Bedaquiline compounds | Granted | PH12005500234 | 18/07/2023 | 18/11/2020 |
| **Philippines** | Bedaquiline 100 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Granted | PH12006502051 | 24/05/2025 | 18/11/2020 |
| **Philippines** | Bedaquiline 100 mg | Bedaquiline to treat latent TB | Filed | PH1-2005-000612 | 08/12/2025 | 20/11/2020 |
| **Philippines** | Bedaquiline 100 mg | Bedaquiline fumarate salt | Granted | PH12009500858 | 03/12/2027 | 19/11/2020 |
| **Philippines** | Bedaquiline 20 mg | Bedaquiline compounds | Granted | PH12010502363 | 18/07/2023 | 18/11/2020 |
| **Philippines** | Bedaquiline 20 mg | Bedaquiline compounds | Granted | PH12005500234 | 18/07/2023 | 18/11/2020 |
| **Philippines** | Bedaquiline 20 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Granted | PH12006502051 | 24/05/2025 | 18/11/2020 |
| **Philippines** | Bedaquiline 20 mg | Bedaquiline to treat latent TB | Filed | PH1-2005-000612 | 08/12/2025 | 20/11/2020 |
| **Philippines** | Bedaquiline 20 mg | Bedaquiline fumarate salt | Granted | PH12009500858 | 03/12/2027 | 19/11/2020 |
| **Philippines** | Bedaquiline 20 mg | Bedaquiline dispersible tablet formulations | Filed | PH12017501331 | 26/01/2036 | 02/07/2020 |
| **Philippines** | Delamanid 50 mg | Delamanid combined with other TB drugs | Filed | PH12015501098 | 04/10/2026 | 20/11/2020 |
| **Philippines** | Delamanid 50 mg | Delamanid combined with other TB drugs | Withdrawn | PH12008500603 | | 18/11/2020 |

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| **Philippines** | Delamanid 50 mg | Delamanid compositions with selected cellulose compounds | Granted | PH12007502673 | 26/11/2027 | 18/11/2020 |
| **Philippines** | Isoniazid/Rifapentine | Isoniazid/Rifapentine dispersible tablet compositions | Withdrawn | PH12016500119 | | 14/10/2020 |
| **Philippines** | Isoniazid/Rifapentine | Isoniazid/Rifapentine coated tablet compositions | Filed | PH12016500120 | 22/07/2034 | 20/11/2020 |
| **Philippines** | Isoniazid/Rifapentine | Rifapentine compound & process | Not Filed | | | |
| **Philippines** | Isoniazid/Rifapentine | Isoniazid use in TB | Not Filed | | | |
| **Thailand** | Bedaquiline 100 mg | Bedaquiline compounds | Withdrawn | TH0801003992 | | 17/02/2021 |
| **Thailand** | Bedaquiline 100 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Filed (opposed) | TH0501002434 | 27/05/2025 | 22/02/2021 |
| **Thailand** | Bedaquiline 100 mg | Bedaquiline to treat latent TB | Filed (opposed) | TH0501005795 | 08/12/2025 | 22/02/2021 |
| **Thailand** | Bedaquiline 100 mg | Bedaquiline fumarate salt | Filed (opposed) | TH0701006189 | 02/12/2027 | 22/02/2021 |
| **Thailand** | Bedaquiline 20 mg | Bedaquiline compounds | Withdrawn | TH0801003992 | | 17/02/2021 |
| **Thailand** | Bedaquiline 20 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Filed (opposed) | TH0501002434 | 27/05/2025 | 22/02/2021 |
| **Thailand** | Bedaquiline 20 mg | Bedaquiline to treat latent TB | Filed (opposed) | TH0501005795 | 08/12/2025 | 22/02/2021 |
| **Thailand** | Bedaquiline 20 mg | Bedaquiline fumarate salt | Filed (opposed) | TH0701006189 | 02/12/2027 | 22/02/2021 |
| **Thailand** | Bedaquiline 20 mg | Bedaquiline dispersible tablet formulations | Filed (opposed) | TH17001004168 | 26/01/2036 | 30/07/2021 |
| **Thailand** | Delamanid 50 mg | Delamanid compositions with selected cellulose compounds | Filed | TH0601003519 | 27/07/2026 | 09/02/2021 |
| **Thailand** | Delamanid 50 mg | Delamanid combined with other TB drugs | Filed | TH0601004877 | 03/10/2026 | 09/02/2021 |
| **Thailand** | Isoniazid/Rifapentine | Isoniazid/Rifapentine coated tablet compositions | Withdrawn | TH1601000414 | | 14/10/2020 |
| **Thailand** | Isoniazid/Rifapentine | Isoniazid/Rifapentine dispersible tablet compositions | Withdrawn | TH1601000296 | | 14/10/2020 |
| **Thailand** | Isoniazid/Rifapentine | Rifapentine compound & process | Not Filed | | | |
| **Thailand** | Isoniazid/Rifapentine | Isoniazid use in TB | Not Filed | | | |
| **Viet Nam** | Bedaquiline 100 mg | Bedaquiline compounds | Granted | VN1200401363 | 18/07/2023 | 13/11/2020 |
| **Viet Nam** | Bedaquiline 100 mg | Bedaquiline to treat MDR TB and/or combinations with | Granted | VN1200601723 | 24/05/2025 | 13/11/2020 |

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| | | other antimycobacterial agents | | | | |
| **Viet Nam** | Bedaquiline 100 mg | Bedaquiline to treat latent TB | Rejected | VN1-2007-01233 | | 12/11/2020 |
| **Viet Nam** | Bedaquiline 100 mg | Bedaquiline fumarate salt | Granted | VN1200900771 | 03/12/2027 | 13/11/2020 |
| **Viet Nam** | Bedaquiline 20 mg | Bedaquiline compounds | Granted | VN1200401363 | 18/07/2023 | 13/11/2020 |
| **Viet Nam** | Bedaquiline 20 mg | Bedaquiline to treat MDR TB and/or combinations with other antimycobacterial agents | Granted | VN1200601723 | 24/05/2025 | 13/11/2020 |
| **Viet Nam** | Bedaquiline 20 mg | Bedaquiline to treat latent TB | Rejected | VN1-2007-01233 | | 12/11/2020 |
| **Viet Nam** | Bedaquiline 20 mg | Bedaquiline fumarate salt | Granted | VN1200900771 | 03/12/2027 | 13/11/2020 |
| **Viet Nam** | Bedaquiline 20 mg | Bedaquiline dispersible tablet formulations | Not Filed | | | |
| **Viet Nam** | Delamanid 50 mg | Delamanid compositions with selected cellulose compounds | Granted | VN200800490 | 19/07/2026 | 21/01/2020 |
| **Viet Nam** | Delamanid 50 mg | Delamanid combined with other TB drugs | Withdrawn | VN1200800834 | | 21/01/2020 |
| **Viet Nam** | Isoniazid/Rifapentine | Isoniazid/Rifapentine dispersible tablet compositions | Rejected | VN1201600461 | | 14/10/2020 |
| **Viet Nam** | Isoniazid/Rifapentine | Isoniazid/Rifapentine coated tablet compositions | Rejected | VN1201600462 | | 14/10/2020 |
| **Viet Nam** | Isoniazid/Rifapentine | Rifapentine compound & process | Not Filed | | | |
| **Viet Nam** | Isoniazid/Rifapentine | Isoniazid use in TB | Not Filed | | | |

## Granted Patents on Hepatitis C Drug Sofosbuvir

| Jurisdiction | Patent Description | Patent Status | Patent Application Number | Expected Expiry Date (dd/mm/yyyy) | Last Updated On (dd/mm/yyyy) |
|---|---|---|---|---|---|
| **China** | Sofosbuvir processes, intermediates & product-by-process | Granted | CN201080032541 | 20/05/2030 | 23/02/2021 |
| **China** | Sofosbuvir processes, intermediates & product-by-process | Granted | CN201510552266 | 20/05/2030 | 29/07/2021 |
| **China** | Sofosbuvir crystalline forms & preparation processes | Granted | CN201410247228 | 31/03/2031 | 29/09/2020 |
| **China** | Compositions comprising crystalline Sofosbuvir | Granted | CN201280058114 | 27/11/2032 | 23/02/2021 |
| **India** | Sofosbuvir active metabolite | Granted (opposed) | IN6087/DELNP/2005 | 21/04/2024 | 08/06/2021 |
| **India** | Sofosbuvir processes, intermediates & product-by-process | Granted | IN4972/KOLNP/2011 | 20/05/2030 | 29/10/2020 |
| **Indonesia** | Sofosbuvir active metabolite | Granted | IDW00200503201 | 21/04/2024 | 16/06/2021 |
| **Indonesia** | Sofosbuvir active metabolite | Granted | IDW00201101421 | 21/04/2024 | 16/06/2021 |
| **Indonesia** | Sofosbuvir processes & intermediates | Granted | IDW00201204454 | 31/03/2031 | 16/06/2021 |
| **Indonesia** | Compositions comprising crystalline Sofosbuvir | Granted | ID00201403478 | 27/11/2032 | 17/11/2020 |
| **Malaysia** | Sofosbuvir active metabolite | Granted | MYPI20041584 | 28/04/2024 | 05/11/2020 |
| **Malaysia** | Sofosbuvir compound (prodrug) | Granted | MYPI20094079 | 26/03/2028 | 06/11/2020 |
| **Malaysia** | Sofosbuvir processes & intermediates | Granted | MYPI2011005625 | 20/05/2030 | 06/11/2020 |
| **Philippines** | Sofosbuvir active metabolite | Granted | PH12005502136 | 21/04/2024 | 18/11/2020 |
| **Philippines** | Sofosbuvir compound (prodrug) | Granted | PH12009501847 | 26/03/2028 | 18/11/2020 |
| **Philippines** | Sofosbuvir processes & intermediates | Granted | PH12011502433 | 20/05/2030 | 19/11/2020 |
| **Philippines** | Sofosbuvir processes, intermediates & product-by-process | Granted | PH12014502684 | 20/05/2030 | 19/11/2020 |
| **Philippines** | Sofosbuvir processes, intermediates & product-by-process | Granted | PH12015502237 | 20/05/2030 | 19/11/2020 |
| **Philippines** | Compositions comprising crystalline Sofosbuvir | Granted | PH12014501133 | 27/11/2032 | 19/11/2020 |
| **Viet Nam** | Compositions comprising crystalline Sofosbuvir | Granted | VN1201401861 | 27/11/2032 | 24/01/2020 |