

THE MEDICINES PATENT POOL

FACILITATING ACCESS — PROMOTING INNOVATION

THE MEDICINES PATENT POOL

Created in 2010 as first voluntary licensing and patent pooling mechanism in public health

medicines patent

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To increase access to new treatments for HIV through licensing of patented medicines

And facilitate innovation e.g. new fixed dose combinations and paediatric formulations

In 2015, expanded mandate to **Hepatitis C** and **Tuberculosis**

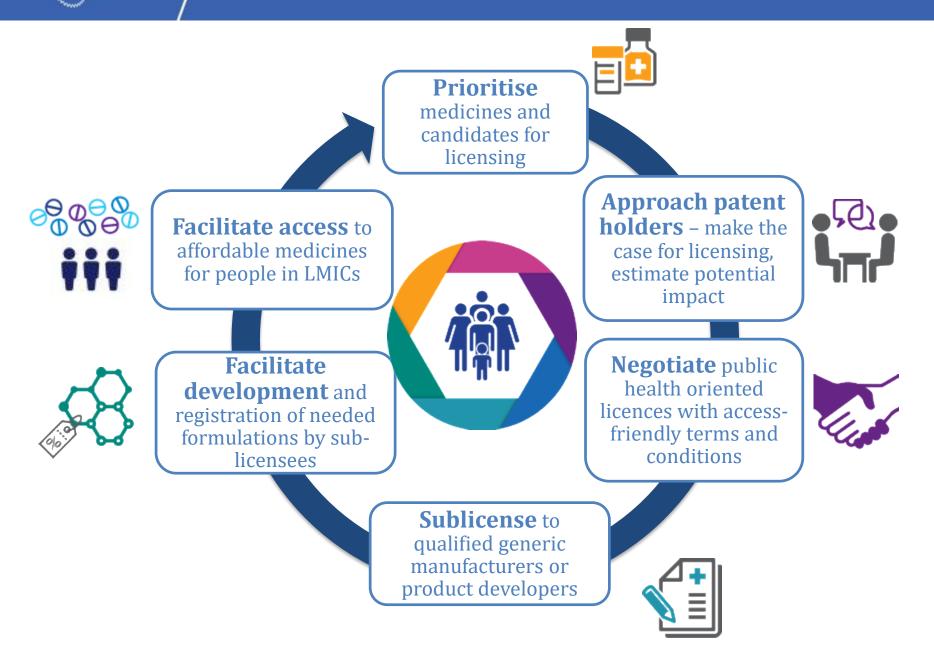
In 2018, decision to expand to **other patented essential medicines**



MPP's activities in HIV, HCV and TB are funded by:



HOW WE WORK



medicines

patent pool

HOW WE WORK



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PUBLIC HEALTH NEEDS GUIDING THE NEGOTIATION PROCESS

PUBLIC HEALTH NEED

Access: Need for affordable access to life-saving medicines



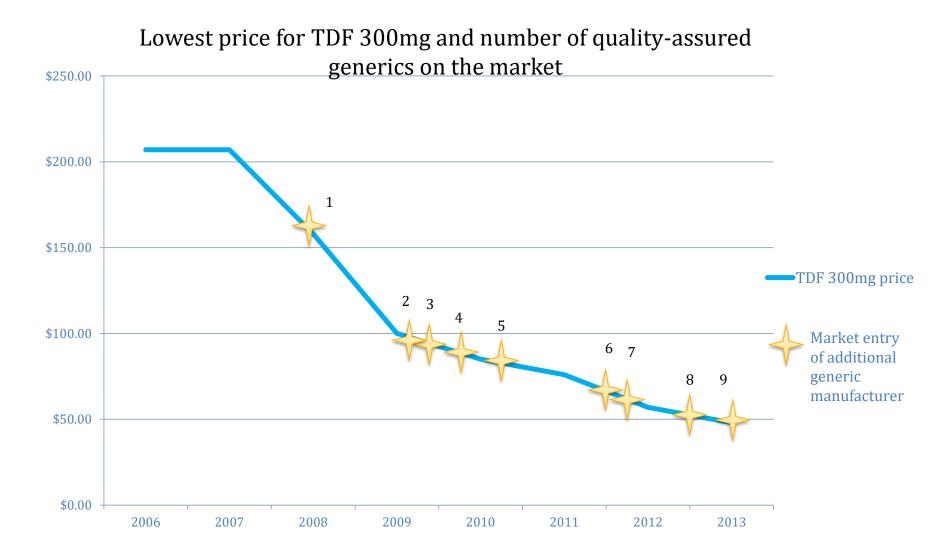
RELEVANT FEATURES IN MPP LICENCES

Licences enable the MPP to sub-license **non-exclusively** to multiple manufacturers to facilitate **competition** and **price reduction**

Example:

- MPP licence on hepatitis C medicine daclatasvir with BMS Sublicensed to 10 generic manufacturers,
- 3 are already on the market with quality product at a price of USD 14 per box (Global Fund Price)

EFFECTS OF COMPETITION ON PRICE EXAMPLE OF TENOFOVIR 300 MG



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TAF

PUBLIC HEALTH NEEDS GUIDING THE NEGOTIATION PROCESS

PUBLIC HEALTH NEED

Innovation: Need for new products that combine various medicines in one pill to improve adherence

FTC



RELEVANT FEATURES IN MPP LICENCES

MPP licences offer the possibility to further innovate by developing new fixed dose combinations

TAF/FTC/DTG

Example: MPP licences with Gilead on TAF/FTC and with ViiV Healthcare on dolutegravir have facilitated the development of a new formulation product

DTG

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PUBLIC HEALTH NEEDS GUIDING THE NEGOTIATION PROCESS

PUBLIC HEALTH NEED

New formulations for children: Need for HIV paediatric formulations that are better adapted for young children



RELEVANT FEATURES IN MPP LICENCES

MPP licences enable licensees to develop new paediatric formulations that address needed gaps

Example: MPP licence with AbbVie is contributing to the development of new HIV formulations targeting the youngest children



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PUBLIC HEALTH NEEDS GUIDING THE NEGOTIATION PROCESS

PUBLIC HEALTH NEED

Quality assurance: Need to ensure that medicines used for treatment scale-up in LMICs are of assured quality



RELEVANT FEATURES IN MPP LICENCES

All MPP licences require approval by generic manufacturers from the **WHO Prequalification** or a **stringent regulatory authority**

Example:

 Three MPP licensees have already obtained USFDA or WHO Prequalification approval for products containing the new HIV medicine dolutegravir patent pool

PUBLIC HEALTH NEEDS GUIDING THE NEGOTIATION PROCESS

PUBLIC HEALTH NEED

Accelerated access:

Need to speed up access to new groundbreaking treatments



RELEVANT FEATURES IN MPP LICENCES

MPP licences are negotiated early in the life cycle of the products and proactive license management **shortens time to market**

Example: Time from approval of HIV medicines to generic competition

Prior to MPP ~ 7-8 years With MPP ~ 3-4 years



"The MPP continues to be the central independent driver of access-oriented licensing in the pharmaceutical industry. Licences agreed via the MPP include the majority of the access-oriented terms and conditions looked for by the Index"

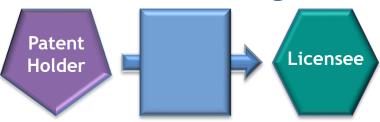
Access to Medicines Index, November 2018



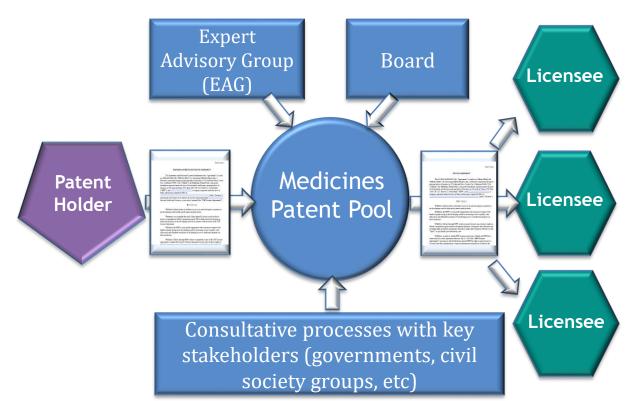
MPP LICENSING VS. TRADITIONAL LICENSING IN PHARMACEUTICAL FIELD

Traditional licensing model

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Licensing model of the MPP



MPP ACCOMPLISHMENTS



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> **13** HIV medicines and 1 HIV platform technology licensed



130+ ongoing pharmaceutical development projects



3 hepatitis C direct-acting antivirals



17 million patient-years of treatments delivered through MPP's generic partners



1tuberculosis drug candidate



535 million

US dollars saved. 2.3 billion expected from already negotiated HIV licences *

* Juneja S, et al "Projected savings through public health voluntary licences of HIV drugs negotiated by the Medicines Patent Pool (MPP)" PLoS ONE 12(5) (2017)

UN Political Declaration on HIV/AIDS (2016), Paragraph 23:

"(...) welcome the broadening of the scope of work of the **Medicines Patent Pool**, hosted by UNITAID, to promote voluntary partnerships to address hepatitis C and tuberculosis, reflecting the importance of integrating the AIDS response into the broader global health agenda"

WHO Health Sector Strategy on HIV/AIDS 2016-21 (page 42)

"Strategies include fostering generic competition, including through, where appropriate, voluntary licences that include pro-access terms and conditions such as those negotiated by the **Medicines Patent Pool**,"

UNAIDS 2016-21 Strategy (Page 83)

"Furthermore, UNAIDS will pursue additional collaboration with the **Medicines Patent Pool**, an initiative funded by UNITAID, to elaborate analyses on the patent landscape of HIV medicines and forecasting of newer HIV-related products."











The MPP's HIV, TB and hepatitis C activities are fully funded by:

