

MEDICINES PATENT POOL - A MODEL FOR INCREASING ACCESS AND INNOVATION OF MEDICINES IN DEVELOPING COUNTRIES

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Innovation on an unprecedented scale

- Since discovery of the Human Immunodeficiency Virus (HIV) in 1980s, **29 new antiretroviral** medicines have reached the market – even more if we include combinations

Need to ensure access for all

- While **15.8 million** people have access to HIV treatment worldwide, there are **37 million** people living with HIV
- How to ensure everybody needing treatment has access at affordable prices?
- How to ensure that new, improved treatments become available faster in developing countries?
- How to facilitate the development of needed paediatric formulations and combination products?

Created in 2010 to increase access to quality, appropriate medicines for people living with HIV in developing countries

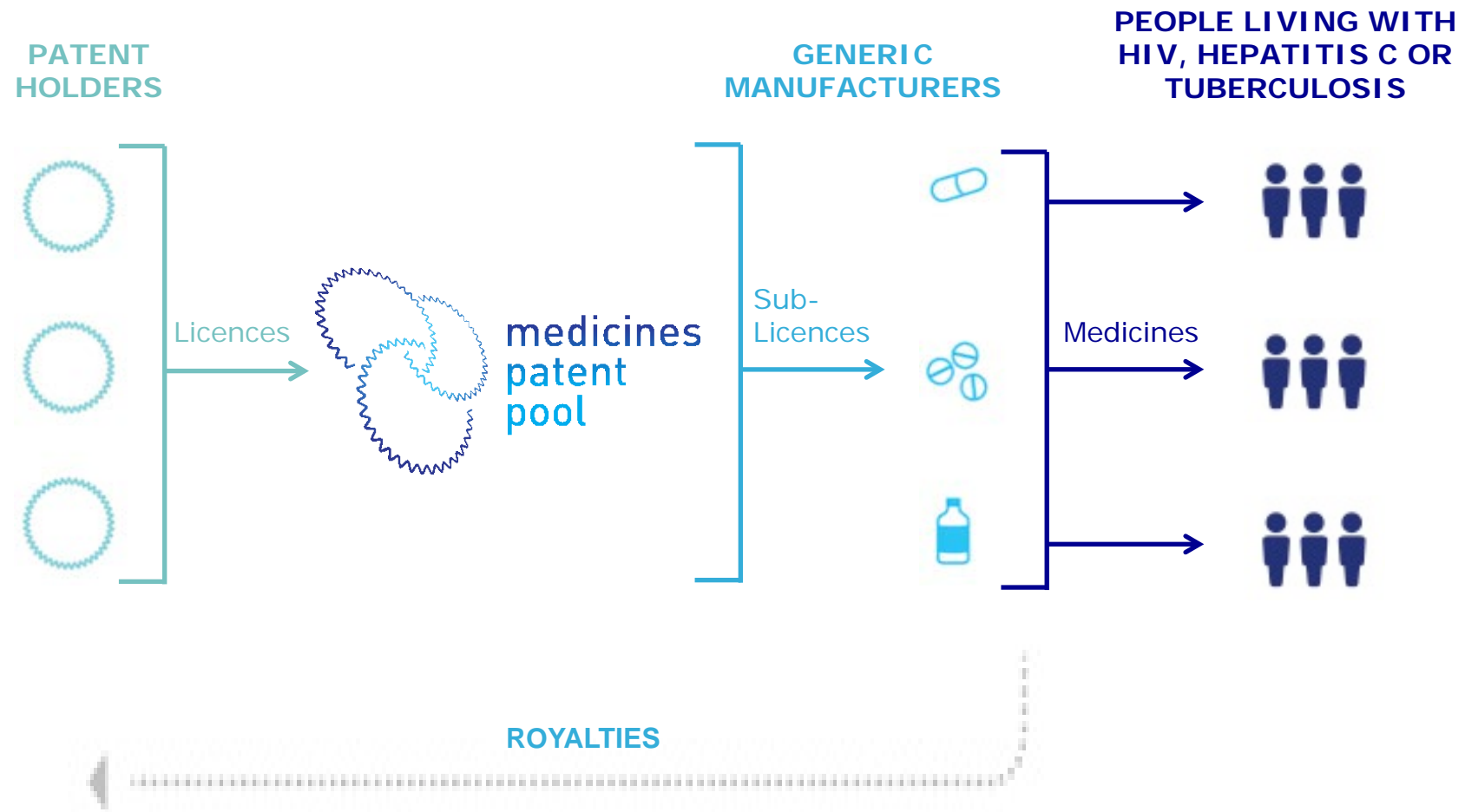
The MPP is a public health voluntary licensing mechanism that partners with all key stakeholders (governments, patent holders, generic manufacturers, civil society and community/patient groups)

Initially focused on HIV alone, has now expanded to HCV and TB

Endorsed by WHO, the UN High Level Meeting on AIDS, the G8 as a promising and innovative public health approach



THE MEDICINES PATENT POOL: A PUBLIC HEALTH VOLUNTARY LICENSING MECHANISM



The MPP was founded and remains fully funded by UNITAID





Share Patents

“Pool” patents & technology through a collaborative voluntary licensing system



Reward Innovation

Ensure continued incentives for innovation



Spur New Innovation

Enable development of new fixed-dose combinations and formulations for children



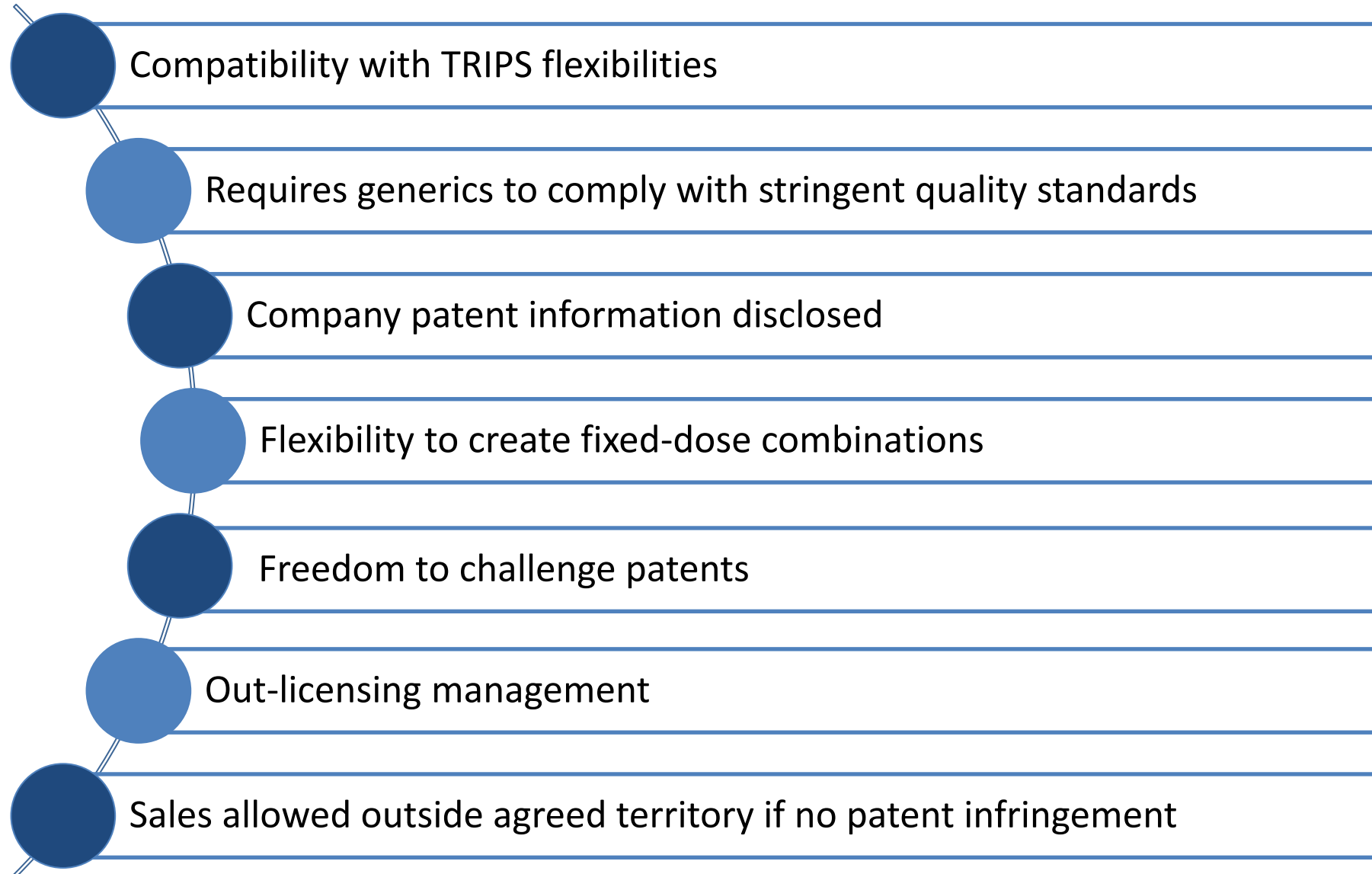
Ensure Access

Accelerate availability of more affordable versions of needed medicines to developing countries



Product Licensed	Low income	Lower middle income	Upper middle income	High income	Undefined	Total	% PLHIV/CL HIV in LMICs
Abacavir (paediatric)	31	53	31	5	1	121	99.3%
Atazanavir	31	46	29	3	1	110	88.8%
Cobicistat	30	42	18	9	4	103	87.4%
Daclatasvir	31	46	30	2	3	112	68.6%
Dolutegravir (paediatric)	31	53	31	5	1	121	99.3%
Dolutegravir	31	53	6	2	0	92	94.2%
Elvitegravir	30	42	17	8	3	100	87.3%
Lopinavir/Ritonavir (paediatric)	31	50	19	2	0	102	98.8%
Lopinavir/Ritonavir (Africa)	26	17	10	2	2	57	80.5%
Raltegravir (paediatric)	31	50	9	2	0	92	98.5%
Tenofovir disoproxil fumarate	30	46	23	9	4	112	92.2%
Tenofovir alafenamide	30	46	23	9	4	112	92.2%

- Non-exclusive, non-restrictive to encourage competition
- Transparent – all licences are public
- Wide geographical scope
- 55% to 80% of middle income countries covered
- Waivers for regulatory data exclusivity
- Tiered royalties where possible to enhance coverage
- Public-Private Market Segmentation to increase geographical scope

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- Compatibility with TRIPS flexibilities
 - Requires generics to comply with stringent quality standards
 - Company patent information disclosed
 - Flexibility to create fixed-dose combinations
 - Freedom to challenge patents
 - Out-licensing management
 - Sales allowed outside agreed territory if no patent infringement

“ Licensing activity, as well as the transparency and flexibility of terms and conditions, is highest when a third-party broker is involved, namely the Medicines Patent Pool....The Index encourages all companies engaged in Voluntary Licensing to meet the high standards demonstrated in the MPP agreements...”

Source: The Access to Medicines Index
2014 p. 110



**Licences with 7
patent holders**

119 countries
receiving ARVs

13 generic partners

9.1 million patient -
years of ARVs

**Licences on 12 ARVs
+ 1 HCV drug**

US\$ 195 million saved

60+ projects with
generic partners

US\$ 2.3 billion
projected savings



abbvie

- Lopinavir
 - Ritonavir
- (separate paediatrics and adults licences)



Bristol-Myers Squibb

- Atazanavir
- Daclatasvir (HCV)



GILEAD

- Cobicistat
- Elvitegravir
- Emtricitabine
- Tenofovir Alafenamide
- Tenofovir Disoproxil



Janssen

- Darunavir (paed) (non-assert)



MERCK

- Raltegravir (paed)



NIH

- Darunavir related



Roche

- Valganciclovir (pricing agreement)



UNIVERSITY OF LIVERPOOL

- Solid dispersion nano technology for HIV

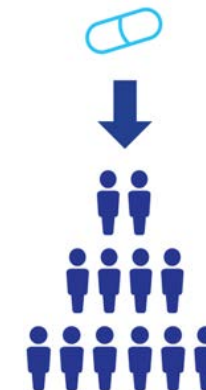
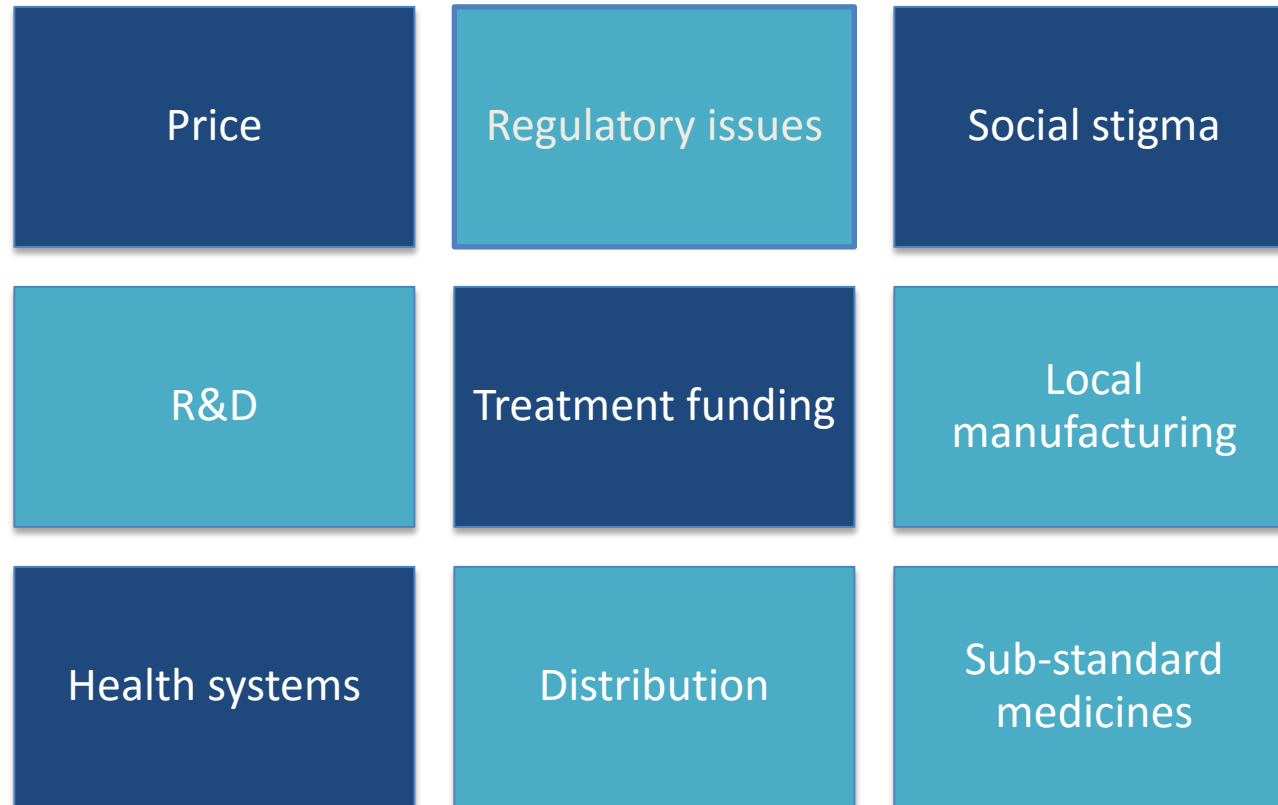


ViiV Healthcare

- Abacavir (paed)
- Dolutegravir (paed)
- Dolutegravir (adults)



MPP is currently running more than 50 development projects
with 13 development partners





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