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Estimating the return on investment of public health voluntary intellectual property licensing

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Article title

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Abstract

The public health voluntary licensing of intellectual property through the Medicines Patent Pool (MPP), a specialised public health agency, increases timely access to quality, affordable, innovative, essential medicines in low- and middle-income countries (LMICs). The impact of this work – which leverages generic competition ahead of patent expiry, accelerates uptake, and drives prices down –outweighs its costs, with a return on investment (ROI) of 90 to 1. This article presents the methodology, assumptions, and findings from estimating the ROI of MPP-supported access to medicine work. It uses the intrinsic valuation approach based on the value of a statistical life, an approach consistent with methodology that peer global health organisations – such as Gavi, the Global Fund, Medicines for Malaria Venture, and Unitaid – have also recently applied. This work also leverages the robust methodology for estimating MPP's health and economic impact that has previously been reported. The methodology presented here to estimate the ROI considers the direct savings and monetises the health impact of MPP's licensing activities from 2010 to 2025 (compared with a set of counterfactual scenarios without MPP, that may or not include some level of generic competition before patent expiry, for example in countries without patent and/or under bilateral – more commercial – licences). It also considers the full costs of achieving this impact (including, among others, the indirect costs of enabling activities of partner organisations that allow MPP's voluntary licensing work to transform into medicine uptake and impact). Results are based on actual and projected costs and outcomes spanning the years 2010-2040. In this article we discuss how a sizeable return is achieved with comparably limited investment.

Keywords

Access to medicines; low- and middle-income countries; equity; health economics; return on investment; impact; voluntary licensing

List of abbreviations

- CEPA Cambridge Economic Policy Associates
- DTG Dolutegravir
- FCDO Foreign, Commonwealth & Development Office
- GDP Gross domestic product
- IP Intellectual property
- LMICs Low- and middle-income countries
- MPP Medicines Patent Pool
- ROI Return on investment
- TLD Tenofovir/lamivudine/dolutegravir
- TRIPS Trade-Related Aspects of Intellectual Property Rights
- UK United Kingdom
- VSL Value of a statistical life
- VSLY Value of a statistical life year
- WHO World Health Organization
- WTP Willingness or ability to pay

Main text

Introduction

In a changing funding landscape for global health, key technical organisations are being asked to demonstrate efficiencies and impact, in other words, a quantifiable and high return on investment (ROI). Recently, the United Kingdom (UK) Foreign, Commonwealth & Development Office (FCDO) gave Unitaid an A+ rating in their annual review, in part owing to Unitaid's ability to deliver strong value for money, as proven by their documented ROI [1,2]. Gavi and the Global Fund have also recently used their respective ROI as part of making investment cases for their replenishments [3-6]. Medicines for Malaria Venture, a product development partnership, has also recently presented an ROI analysis [7]. The Medicines Patent Pool (MPP), a public health agency founded by Unitaid specialising in licensing intellectual property (IP) to increase earlier and broader access to quality generic health technologies in low- and middle-income countries (LMICs), has not previously reported an ROI [8-11]. Here, we introduce a newly developed approach to estimate MPP's ROI, building on an existing robust impact assessment methodology [12].

The work of MPP has historically centred on voluntary licensing, an approach whereby a paten-holding originator pharmaceutical company (or other product development entity) agrees to allow one or more third party generic manufacturers to develop, register, manufacture, and/or distribute an active pharmaceutical ingredient and/or a finished medicine formulation (or finished pharmaceutical product). By providing access to a large, otherwise non-addressed, LMIC market, licensed generic manufacturers that generally do not have to recoup large research investments are able to optimise economies of scale – create efficiencies – and drastically reduce the costs of goods and resulting medicine prices in a way that does not threaten priority commercial markets of originators. Voluntary licensing through MPP as a specialised licensing agency reduces bilateral licensing negotiation and long-term management costs – until patent expiry – for the patent holder. It also effectively keeps public-health access and originator commercial territories separate, which helps minimise the risk that high-income countries use lower (LMIC) external reference pricing that challenges the business model for recovering originators' research and development costs [8].

In addition, cost-recovery transfers from LMICs to originator commercial markets remain negligible, as most voluntary licensed territories would either be of limited market size or profit margins for the originator, depending on their chosen business model (low-volume high-price vs high-volume low-price).

Voluntary licences have become a routine IP management solution to financial inequities causing a lack of or delayed access to innovative HIV medicines in LMICs, and recent years have seen the mechanism being applied in additional therapeutic areas, including HCV, TB, COVID-19, and oncology. MPP's work has also been shown to produce both economic and health returns by allowing access to quality generic versions of innovative medicines several years prior to relevant patent expiries [12-19]. From 2010 until the end of 2024, MPP licences enabled the supply of 52.2 billion doses of medicines (equivalent to 142 million patient years treated) in 148 countries, leading to 42.9 million disability-adjusted life years (DALYs) averted, including 1.12 million DALYs averted specifically by MPP's incremental contribution that has led to the uptake of 5.5 million additional patient-years treated (over and above what originator companies may have done, including bilateral licensing)[1]. This work allowed, by the end of 2024, direct economic savings for the global health community on the order of 2.3 billion USD from access to better medicines that have also been more affordable than the previous standard of care.

However, while voluntary licensing is a central element of global access to medicines in some disease areas (in particular where a commercial market exists in high-income countries), its propagation beyond large infectious diseases (such as HIV and HCV) has not yet taken place at a similarly meaningful scale. For neglected tropical and other diseases of poverty that almost entirely exist in lower-income countries and have only limited commercial value for originators (who may still invest in these diseases with philanthropic goals, often not seeking to make profits, but only hoping to recover their investments), voluntary licensing may not be the preferred approach. Other models, such as product development partnerships (e.g., via the Drug for Neglected Diseases Initiative, the Global Antibiotic Research and Development Partnership, or the Medicines for Malaria Venture) may work better in these cases. Similarly, voluntary licensing may not be the

[1] MPP's output and impact figures are updated annually and published in June at https://medicinespatentpool.org/progress-achievements/impact. The impact figures referred to in this paper and used for the ROI calculations were based on output and impact figures published in June 2025.

most suitable mechanism to enable affordable access in high-income countries with larger willingness and capacity to pay and where price regulations that leverage central negotiation and external reference pricing (compared to other high-income countries) may be more adapted, efficient, and compatible with research-based pharmaceutical companies' financial realities.

Indeed, voluntary licensing is not the solution to all access to medicine challenges, and only one solution among a larger access to medicine toolbox that includes various approaches such as: patient assistance programmes; distribution agreements to reduce supply chain mark-ups; second brand market segmentation strategies; tiered or differential pricing based on country-income or other economic metrics; short and long term donations; as well as government controlled approaches defined by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), such as stringent patenting criteria, patent opposition mechanisms, and compulsory licences [20,21]. Some of these, as well as additional mechanisms, that can be grouped together as market shaping approaches (such as advanced purchase agreements, price negotiations, demand forecasting, and pooled procurement), can often work in synergy and leverage and amplify the potential for access to affordable quality generics enabled through voluntary licensing [22].

In this paper, we build on MPP's existing impact assessment methodology and present a framework to consider the incremental health and economic impact of voluntary licensing via MPP in the context of its direct and indirect ecosystem enabling costs [12,23]. The resulting ROI provides a useful metric to further assess the added value of MPP's voluntary licensing-based access to medicine work, and the discussion explores various essential dependencies for it and its impact to take place.

Methods

Global health organisations increasingly report an ROI by monetising health benefits using the intrinsic valuation approach based on the value of a statistical life (VSL, or value of a statistical life year: VSLY) [2-7,24-29]. This intrinsic approach assigns value to additional years of life based on individuals' willingness or

ability to pay (WTP) to reduce their risk of injury and death. This value is scaled using a price elasticity factor that adjusts a reference VSL to reflect differences in income levels across countries. A less-used approach is instrumental valuation, which assigns a value to additional years of life to the extent that they increase productive economic work. Some global health organisations report ROI numbers using both approaches or, like the World Health Organization (WHO) in its second investment case, combine these values into a single "full income" ROI estimate [30]. While the full-income approach was more common in the academic literature published until 2019, in recent years the intrinsic valuation approach has become more common as a standardised attempt to calculate the social value of a life year. The *Lancet Commission on Investing in Health* was updated in 2024 and, while continuing to use language around a "full income" approach, it effectively applied an underlying methodology similar to the intrinsic approach using a VSLY methodology based on 2019 Harvard guidelines, which have become the standard used by various large global health organisations – now including MPP [31,32].

The health and economic impact of MPP licensing agreements has been reported for several years, on the basis of a peer-reviewed methodology initially applied to two case studies for HIV and HCV medicines [12]. This methodology was subsequently expanded to include more medicines/licences for HIV (6 licences for 4 medicines), HCV (1 licensed medicine), COVID-19 (2 licensed medicines), and cancer (1 licensed medicine). Using impact estimates along with information on MPP's direct expenditure, MPP has previously reported a simplistic benefit-cost ratio that did not (1) monetise health impact; (2) include the costs of enabling activities by partner organisations; and (3) align with approaches used by other global health organisations. As such, MPP has not, until now, fully calculated an ROI.

The organisation's newly developed ROI estimation methodology discussed in this paper follows the approach recommended in the academic literature (in particular, the standard Harvard guidelines directing implementation of the intrinsic valuation approach) and uses key assumptions aligned with other global health organisations to ensure credibility and consistency [32]. MPP's incremental impact: health system cost savings and health benefits (expressed as DALYs averted) is collated from existing MPP impact models, following MPP's published impact methodology [12,23]. The financial value of health benefits is estimated

189 by monetising DALYs averted using the intrinsic valuation approach based on the VSL, starting from a United
190 States benchmark value that is scaled to the average purchasing power parity-adjusted gross domestic
191 product (GDP) per capita for each disease area weighted by LMIC disease burden. This ensures consistency
192 with analyses of peer global health organizations, such as the Global Fund and Unitaid [33,34]. Benefits are
193 only assessed for MPP licensing activities for which impact models and calculations were available at the
194 end of 2025 (calculating cost-savings and/or DALYs averted achieved until the end of 2024 and projected
195 until a few years following patent expiry when annual incremental MPP licensing impact becomes null). As
196 such, benefits relating to activities for which impact is uncertain or not quantified are not included.
197
198 Mirroring benefits, costs are counted for the entire period of modelled licence impact: effectively between
199 2010-2040 (for licences concluded before the end of 2025). Invested costs include:
200 • Past funding to MPP (up to 2025, inclusively, as reported in MPP's annual financial statements as the full
201 accounting costs for the organisation, including all overheads, minus the project costs of the mRNA
202 technology transfer programme, which is not voluntary licensing work and for which it is too early to
203 assess potential benefits, particularly in terms of the metrics needed for an ROI calculation, such as
204 DALYs averted) [35].
205 • Future MPP costs of managing existing licences (as an estimated share of future budgets that will be
206 required for ongoing licence management and policy and uptake activities for licences signed until the
207 end of 2025 – profiled to decrease over time as individual licences reach patent expiry).
208 • Upstream partner costs for creating an enabling environment in which licensing to MPP can take place
209 (given that MPP licensing often occurs as a result of various projects and initiatives focused on
210 supporting access in LMICs, and intensive technical and legal discussions involving third parties,
211 including global health organisations, funders, implementers, civil society, and communities. ROI
212 calculations include an approximate assessment of these costs incurred by these groups that would not
213 have otherwise been incurred in the absence of a mechanism for voluntary licensing, such as MPP's).
214 • Downstream partner costs required to facilitate the uptake of MPP-licensed products (accounting for
215 the costs of accelerating uptake – such as product registration, normative guidance adoption, training

of staff, demand creation, and procurement and delivery planning – that may not have taken place in absence of MPP's contribution).

- Donor operating costs (i.e. the costs incurred to raise the funds allocated to MPP, as well as to undertake due diligence, governance and oversight, and day-to-day management activities associated with grant making and monitoring).

Modelling is performed across a series of low, central, and high ROI scenarios to estimate a central value and a plausible [low – high] ROI range; sensitivities are similarly built by varying specific parameters (table 1). These are presented further below. Costs are normalised to take into account inflation and a 3% annual discount rate [36]. The macro-enabled Excel spreadsheet used to estimate the ROI across the various scenarios and sensitivities – including input parameters, intermediate calculations, and other mechanics – is available in the Zenodo repository at: https://doi.org/10.5281/zenodo.19711103.

Table 1. Key variables of modelling scenarios and sensitivity analysis. Impact scenarios are based on the extent of generic competition (and associated price reductions), and on the relative clinical effectiveness of focus vs comparator products [12]. Return (benefits) side parameters are highlighted in green, investment (costs) side parameters are in red, and parameters applied to both returns and investments are in purple. The parameter set for the selected main central intrinsic valuation approach results presented as lead numbers for this analysis are highlighted in blue.

	Selected approach: Intrinsic valuation			**Sensitivity: Instrumental valuation**			**Sensitivity: Country weighting**			**Sensitivity: Partner costs**			**Sensitivity: Discount rate**		
Parameters affecting the calculation of returns															
Impact scenario [12]	Low	Central	High	Low	Central	High	Low	Central	High	Low	Central	High	Low	Central	High
Methodology	Intrinsic			Instrumental			Intrinsic			Intrinsic			Intrinsic		
GDP weighting	By disease burden			By disease burden			By country impact			By disease burden			By disease burden		
Parameter affecting the calculation of investments															
Upstream and downstream partner costs scaling	1			1			1			0	1	2	1		
Parameter affecting the calculation of returns and investments															
Discount rate	3%			3%			3%			3%			5%	3%	0%

Results

It is estimated that every dollar invested in MPP's voluntary licensing activities between 2010 and end-2025 generates an estimated 90 [27 – 181][2] dollars in health system savings and monetised health benefits (Table 2 and Figure 1). This arises from large economic returns from access to more affordable, better treatments (compared to previous standards of care) in a large number of countries (148 by the end of 2025), compared with the relatively limited costs of MPP and enabling partner activities.

On the return side, modelled estimates amount to a total of 36.9 billion USD: 4.43 billion USD from direct health system cost savings created by increased generic competition leading to lower prices, plus 32.5 billion USD from the monetised health benefits (estimated using the intrinsic valuation approach) of 3.83 million DALYs averted projected by 2040. On the other hand, costs are on the order of 409 million USD: 124 million USD in past funding to MPP (up to 2025, inclusively); 8.39 million USD in future MPP costs of managing existing licences; 182 million USD in upstream partner organisation costs to create the enabling environment for licensing to MPP to take place; 74.5 million USD in downstream partner costs required to facilitate the uptake of MPP-licensed products; and 19.9 million USD for donor operating costs.

MPP's interventions represent a small operational footprint that builds on existing global public procurement of health commodities and healthcare service delivery systems in LMICs. As such, MPP can achieve a high ROI because voluntary licensing can both accelerate access to life-improving medicines at scale (and create positive health outcomes – Figure 1-B and Table 2), while also being cost saving due to reduced drug prices (often below those of previous standards of care that MPP-licensed products contribute to replace – Figure 1-B and Table 2).

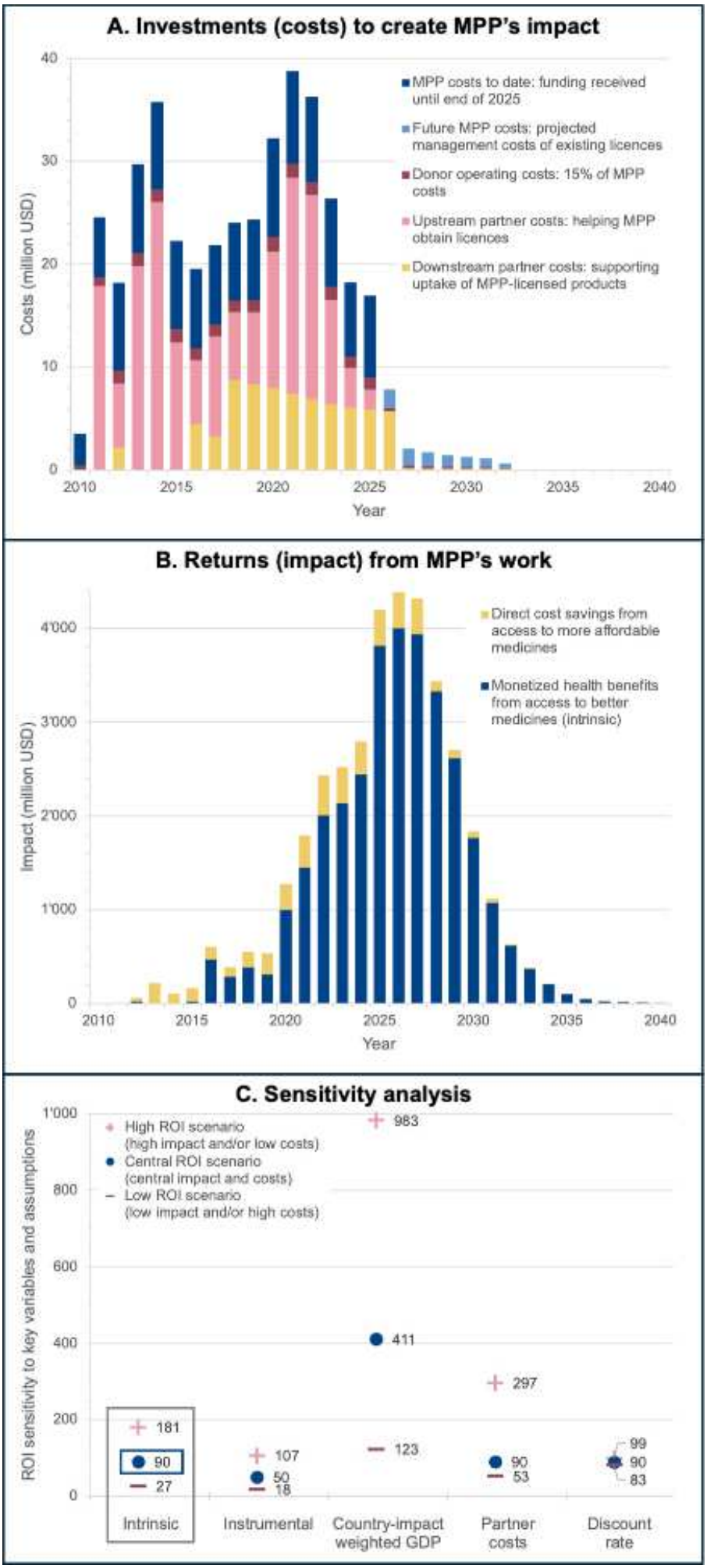
[2] The values presented correspond to central [low – high] scenarios.

Table 2. ROI calculation on a per year per category basis. All costs are rounded and shown as USD million accounted for inflation and a 3% annual discount rate, with 2024 USD as the reference or base year. Return side figures are highlighted in green, while investment side figures are in red.

	Return / impact / benefits					Investment / Costs				
	Costs saved	**DALYs averted**	**Monetized DALYs**	**Sum** (million USD)	**Past MPP funding**	**Future MPP licence management costs**	**Upstream partner costs**	**Downstream partner costs**	**Donor operating costs**	**Sum** (million USD)
2010	-	-	-	-	3.1	-	-	-	0.5	4
2011	-	-	-	-	5.8	-	17.9	-	0.9	25
2012	42	1,920	20	62	8.5	-	6.2	2.2	1.3	18
2013	218	-	-	218	8.6	-	19.8	-	1.3	30
2014	106	40	-	107	8.4	-	26.0	-	1.3	36
2015	143	1,970	22	165	8.5	-	12.4	-	1.3	22
2016	137	40,230	469	606	7.7	-	6.2	4.5	1.2	20
2017	103	24,770	285	389	7.7	-	9.7	3.3	1.2	22
2018	165	33,730	387	552	7.6	-	6.6	8.7	1.1	24
2019	226	33,040	310	536	7.8	-	7.0	8.3	1.2	24
2020	277	95,580	997	1274	9.6	-	13.2	8.0	1.4	32
2021	340	139,130	1451	1790	9.0	-	21.0	7.4	1.4	39
2022	430	233,680	2004	2433	8.3	-	19.8	6.9	1.2	36
2023	388	244,150	2133	2521	8.6	-	10.1	6.4	1.3	26
2024	352	275,930	2442	2795	7.2	-	3.9	6.1	1.1	18
2025	383	445,080	3813	4196	7.9	-	1.9	5.9	1.2	17
2026	382	468,180	3999	4382	-	1.9	-	5.7	0.3	8
2027	383	487,710	3936	4319	-	1.7	-	0.2	0.2	2
2028	112	416,830	3326	3437	-	1.4	-	0.2	0.2	2
2029	92	336,570	2612	2704	-	1.1	-	0.2	0.2	1
2030	67	228,100	1766	1833	-	1.0	-	0.2	0.2	1
2031	48	138,990	1073	1120	-	0.9	-	0.2	0.1	1
2032	15	80,260	618	633	-	0.4	-	0.2	0.1	1
2033	9	48,380	371	380	-	-	-	-	-	-

2034	5	26,970	207	211	-	-	-	-	-	-
2035	2	13,330	102	104	-	-	-	-	-	-
2036	1	6,320	48	49	-	-	-	-	-	-
2037	-	3,270	25	25	-	-	-	-	-	-
2038	-	2,060	16	16	-	-	-	-	-	-
2039	-	1,580	12	12	-	-	-	-	-	-
2040	-	1,390	10	10	-	-	-	-	-	-
Sub-total	4,430	3,830,000	32,500	36,900	124	8.39	182	74.5	19.9	409
ROI										**90**

Figure 1. Overview of the ROI from MPP's work on access to medicines. (A) Investments by year and type (with the intent of being as comprehensive as possible). (B) Returns by year and type (modelled estimates). Costs and savings are considered, using a time-discounted, consistent-price basis. (C) Sensitivities to key variables and assumptions (as outlined in Table 1 and detailed in Table 3). The intrinsic and instrumental valuation approaches are compared. The effective GDP is weighted by LMIC disease burden in the central scenario, whereas the sensitivity weights GDPs according to the distribution of MPP-licensed products' impact. Partner costs vary from being completely omitted (high ROI sensitivity), to being approximately twice as much as the direct costs of MPP (central scenario) and approximately four times as much (low ROI sensitivity). The discount rate used for both costs and benefits and applied to both past and future impact figures is varied around the central value of 3%: 5% for the low ROI sensitivity and 0% for the high ROI sensitivity. MPP's ROI considers impact/returns from the 8 most impactful medicines licensed to MPP by the end of 2025; this includes actual and projected related costs and impact spanning the years 2010-2040 (with impact gradually stopping to accrue following relevant patent expiries). The low-high range shown for MPP's ROI comes from scenarios in MPP licence impact models based on the extent of generic competition (and associated price reductions), and on the relative clinical effectiveness of focus vs comparator products. The [low – high] ranges presented do not originate from sampling and are thereby not statistical confidence intervals [12].


A. Investments (costs) to create MPP's impact
Costs (million USD)
Year
MPP costs to date: funding received until end of 2025
Future MPP costs: projected management costs of existing licences
Donor operating costs: 15% of MPP costs
Upstream partner costs: helping MPP obtain licences
Downstream partner costs: supporting uptake of MPP-licensed products
B. Returns (impact) from MPP's work
Impact (million USD)
Year
Direct cost savings from access to more affordable medicines
Monetized health benefits from access to better medicines (intrinsic)
C. Sensitivity analysis
ROI sensitivity to key variables and assumptions
High ROI scenario (high impact and/or low costs)
Central ROI scenario (central impact and costs)
Low ROI scenario (low impact and/or high costs)
Intrinsic
Instrumental
Country-impact weighted GDP
Partner costs
Discount rate

When calculating MPP's ROI, we have adopted a conservative approach to avoid overestimation, and our assumptions have generally leaned toward the less favourable option whenever uncertain. Upstream and downstream partner costs were a major sensitivity in this analysis. It is challenging to estimate exactly how much partners spend (1) upstream to enable and support MPP licensing and (2) downstream to facilitate the wide and rapid rollout of these medicines and thereby create the corresponding health and economic impact (Figure 1-A). In the central scenario estimated partner costs are substantial and represent approximately twice the amount of direct MPP costs. When doubling partner costs (to four times greater than MPP costs), the ROI reduces to 53:1 (compared with 90:1) – conversely, removing partner costs entirely increases the ROI to 297:1 (this is presented as a sensitivity in Figure 1-C and Tables 1-3).

Additionally, and in line with the Global Fund and Unitaid approaches, MPP's ROI calculation weighs effective GDP by LMIC disease burden (using UNAIDS-reported AIDS-related deaths as a proxy) when calculating the intrinsic value of health. Weighting by individual countries where MPP-licensed products have been procured would yield a much higher ROI (411:1) due to the high share of MPP's health benefits taking place in middle-income countries with larger per capita GDPs (this is presented as a sensitivity in Figure 1-C and Tables 1-3) [12]. We have decided not to use this approach (i.e. effective GDP weighted according to product footprint) as it would imply a higher value of life for people in higher-income countries compared to individuals living in lower-income countries, which would be at odds with the equity goals of MPP's and other global health partners' work.

Another sensitivity analysis performed concerns the discount rate whereby past and future costs and benefits are normalised to the present. Varying the rate around the central value of 3%, which is widely used in health economics and by other global health organisations in their ROI calculations, yields minor variations in the resulting ROI: 83:1 with a 5% rate and 99:1 with no discount, i.e. a 0% rate [32].

Table 3. Key results of modelling scenarios and sensitivity analysis. Key parameters for each of these scenarios and sensitivities are defined in Table 1. The colour scheme highlights the central presented results (blue) and the parameters that are varied on the return (green) and investment (red) sides (in line with parameter details and colours of Table 1).

	Selected (intrinsic) approach			**Instrumental Approach**			**Country weighting sensitivity**			**Partner costs sensitivity**			**Discount rate sensitivity**		
ROI scenarios	Low	Central	High	Low	Central	High	Low	Central	High	Low	Central	High	Low	Central	High
Returns (impact)	11,000	36,900	73,900	7,470	20,500	43,700	50,400	168,000	402,000	36,900	36,900	36,900	37,900	36,900	34,800
Investments (costs)	409	409	409	409	409	409	409	409	409	696	409	124	455	409	353
ROI	27	90	181	18	50	107	123	411	983	53	90	297	83	90	99

In a similarly conservative approach, items included as returns are not an exhaustive representation of benefits that could be attributed to MPP, whereas costs are included more comprehensively. Not currently reflected in the benefits side of the ROI calculation are the following: (1) licences for which impact remains limited or highly uncertain; (2) licences that were signed too recently to assess (e.g., cabotegravir for HIV pre-exposure prophylaxis and treatment); (3) new licences that have been , or may be, signed from 2026 onwards (e.g., baloxavir marboxil for influenza); (4) impact from activities other than the voluntary licensing of medicines (e.g., the WHO/MPP mRNA Technology Transfer Programme, the use of MPP's strategic information tools such as MedsPaL and LAPaL, or licences for upstream technologies, vaccines, or diagnostics, such as agreements through the WHO COVID-19 Technology Access Pool and Health Technology Access Programme) [37-40]. MPP costs, on the other hand, include licensing efforts at large, as well as expenses related to strategic information tools (they do not, however, cover the costs of the WHO/MPP mRNA Technology Transfer Programme, which are considered out of scope). The positive spillover effects of licensing on trends in access to medicines and health technologies more broadly (e.g., best practices championed by MPP that influence direct bilateral licences between originator and generic manufacturers); and equity aspects of improving access to key medicines for marginalised and vulnerable populations, are also not considered.

Discussion

MPP's ROI highlights the organisation's role as a catalytic enabler that can create large impact from relatively limited resources. Notably, the nature of MPP's operations does not require investment in high-cost activities/processes – such as clinical trials and procurement/delivery, which is not the case for many "implementing" global health organisations, such as product development partnerships and pooled procurement mechanisms. However, MPP's impact clearly relies on such essential investments in healthcare systems by its partners and peers in the global health community (medicine delivery, in particular). MPP's ROI is thereby possible precisely *because* of organisations such as Unitaid (which holistically invests in accelerating the development and introduction of new products) and the Global Fund

(with enables uptake at scale through massive investments in the procurement and delivery of medicines and accompanying services). However, in most cases (in particular HIV, for which our modelling considers treatment coverage as extraneous and independent to MPP's licensing work), these investments are assumed to be equal in counterfactual and factual scenarios (i.e. without and with MPP).

In fact, these organisations have highly complementary roles, and each would separately have a lower ROI if it were not for the synergistic contributions of others. For example, Global Fund interventions lead to very large impact; they also require significant expenses for the procurement of medicines (including generic medicines licensed through MPP), diagnostics, and other health commodities, as well as payments for the implementation of health services; policy and advocacy work; community awareness, demand creation, and quality and stock out monitoring; and stakeholder engagement, governance, and accountability systems. Without the Global Fund and similar infrastructure and delivery programmes, MPP's ROI would be lower. Recognising this kind of synergy, the Global Fund and Unitaid have previously estimated that innovation (enabled through Unitaid investments) increases the Global Fund's ROI by 16% [41,42]. Similarly, as one of Unitaid's grantees, MPP is an important contributor to Unitaid's ROI, which includes the modelled impact of HIV and HCV medicines licensed through MPP and covered in this analysis, and which the UK's FCDO described as "one of the best returns on investment for donor funds in global health" [1,2].

Our analysis shows that the ROI for voluntary licensing is particularly significant when the focus of such collaboration leverages complementary and synergistic work and focuses on highly impactful products such as WHO-recommended first-line dolutegravir (DTG)-based HIV treatment. For the MPP licence for DTG, which is the largest contributor to MPP's impact and ROI, the following factors are key:

- DTG-based HIV treatment represents a very large volume: 26 million people were on generic MPP-licensed DTG-based treatment regimens in LMICs in 2025. Not all of this uptake can be attributed to MPP, and the ROI calculations presented in this paper align with counterfactual licensing scenarios presented earlier whereby wide access to generics would still have taken place without MPP (albeit not as much), thanks to the patent holder's stated bilateral voluntary licensing policy at the time (which MPP helped further expand, thereby creating truly additive impact) [12].

- Compared with efavirenz-based treatment (as the previous standard of care), DTG creates significant health benefits: averting 0.98 [0.24 – 2.02] more AIDS-related deaths per hundred person-years treated [43].
- DTG is procured at an increasingly lower cost than the previous standard of care: the full first-line adult generic HIV treatment combination regimen (of tenofovir/lamivudine/dolutegravir, known as TLD) is now available at less than 33 USD per year through the Global Fund [44]. This price has also regularly decreased since the launch of generic TLD at 75 USD per year in 2017 [45]. TLD is now available at less than half its launch price – and at less than half the price of the previous standard of care, efavirenz. While TLD affordability has likely contributed to enabling more people to be put on HIV treatment, our impact model considers HIV treatment coverage as an exogenous variable, relying instead on existing UNAIDS and WHO treatment uptake data and forecasts (and assuming equal HIV treatment coverage in counterfactual and factual scenarios) [12]. This decision recognises that treatment scale-up would have happened anyway in absence of MPP, although with fewer people/countries able to access DTG products (and instead relying on EFV-based regimens). The decision was made to avoid the complications of attributing HIV treatment scale-up (which would represent both additional costs and health impact) to a single global health mechanism (i.e. voluntary licensing through MPP); it represents an additional illustration of having applied a conservative approach to avoid over-estimating impact and ROI. In some cases, though, MPP impact modelling does assume some level of treatment scale-up being triggered by the affordable availability of a previously non-affordable medicine (often when there is no good standard of care, or no therapeutic option available at all). This is the case mostly for acute infectious diseases (such as COVID-19 and HCV infections), while chronic diseases with stable treatment cohorts (such as HIV) are modelled with fixed treatment coverage that is independent of MPP's intervention.

Conclusions

The voluntary licensing of priority medicines of high public health importance – such as those recommended by WHO normative guidance and/or included in the WHO Model Lists of Essential Medicines – leads to an

ROI of 90:1 (with low – high scenarios standing at 27:1 and 181:1, respectively]. This is made possible in the context of a range of complementary external pieces of work enabling rollout at scale. The converse is also true: the impact of large global health interventions is made more efficient and thereby increased by the possibility of sourcing optimal, innovative, and affordable quality-assured generic medicines many years prior to patent expiry. This important role of generic medicines was recognized early on in the global response to HIV [46]. As such, MPP and international, regional, and national funding and procurement mechanisms remain catalytic, complementary, impactful, and necessary joint investments in global health.

This health economics analysis is particularly relevant in a globalised world of increasingly tight financial resources for global public health work [47]. It further documents how multiple complementary global health mechanisms create synergistic added value while addressing the basic human right to health. Voluntary licensing, as an approach that can balance IP rights with health access equity, is particularly relevant in this context. As a central element of negotiations taking place on pathogen access and benefit sharing in the context of the WHO's Pandemic Treaty, voluntary licensing can provide a proven model for equitable access to medical countermeasures, and the evidence presented here further highlights its potential impact [48-50]. Moving forward, continued investments in MPP's work will open the way to replicating the health and economic returns observed to date, especially if efforts to expand access to priority medicines for infectious and noncommunicable diseases (such as those already identified by MPP for HIV, respiratory syncytial virus, immuno-oncology, and metabolic disorders) succeed [51].

Declarations

- Ethics approval and consent to participate

  Not applicable

- Consent for publication

  Not applicable

- Availability of data and materials

The dataset supporting the conclusions of this article is available in the Zenodo repository, https://doi.org/10.5281/zenodo.19711103.

- Competing interests

SM, RF, EB, JC, and CG are employees of the Medicines Patent Pool (MPP), which is funded by Unitaid, the Swiss Agency for Development and Cooperation, the French Ministry for Europe and Foreign Affairs, the German Agency for International Cooperation, the Ministry of Foreign Affairs of Japan, the Government of Canada, the Government of Belgium, the Government of Flanders, and Coefficient Giving. Funders were not involved in this work. CVD and OBH are employees of Cambridge Economic Policy Associates (CEPA) and have acted as consultants for MPP for this and previous impact assessment projects. The work presented in this paper was led by MPP employees, supported by commissioned contributions from CEPA health economics consultants; this represents an evidence-based self-assessment building on previously published impact assessment methodologies, including by several of the same authors, who invite independent investigators to replicate and build on their findings.

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- Authors' contributions

SM: Conceptualization, Supervision, Validation, Visualization, Writing – original draft, Writing – review and editing. RF: Resources, Investigation, Data curation, Conceptualization, Supervision, Validation, Writing – review and editing. OBH: Methodology, Data curation, Investigation, Formal analysis, Validation, Visualization, Writing – original draft, Writing – review and editing. CvD: Methodology, Data curation, Investigation, Formal analysis, Validation, Visualization, Writing – original draft, Writing – review and editing. EB: Conceptualization, Project administration, Writing – review and editing. JC:

Conceptualization, Project administration, Funding acquisition, Writing – review and editing. CG: Funding acquisition, Writing – review and editing.

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- Authors' information (optional)

Not applicable

Additional files

ROI__MPP_voluntary_licensing__2026.xlsm (available at: https://doi.org/10.5281/zenodo.19711103)

Return on investment model

This macro-enabled Excel spreadsheet includes data inputs and calculation sheets to estimate the return on investment (ROI) of the Medicines Patent Pool (MPP) voluntary licensing work to support access to medicines in low- and middle-income countries (LMICs).

ROI__Graphical_abstract.png

Graphical abstract

This graphical abstract visually summarizes the work presented. It is made available as supporting material and as a tool to help disseminate the study findings.

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