Financial Impact of Medicines Patent Pool: I-MAK/ITPC Counter Analysis

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For any public health intervention, a high-quality impact analysis is critical to shaping and prioritizing policies, and ensuring that the intervention will achieve its intended benefit. An impact analysis with ill-informed or inflated assumptions may over-promise results that are unrealistic. This runs the risk of masking further improvements that may be needed to achieve the desired impact, and can even divert focus and resources away from other approaches.

When evaluating the benefits of the Medicine Patent Pool (MPP), it is therefore important to ensure that the methodology and assumptions underlying its impact analysis are sound. This means ensuring that its analyses are based on realistic (and not overly optimistic) scenarios; use appropriate historical data to inform key assumptions; and compare results to the counterfactual (i.e. status quo) scenario to determine direct incremental benefits.

Using these principles, we have prepared the following analysis as a response to claims made by the MPP about its economic benefits, as elaborated in "Annex 10: Economic Benefits of the Pool" presented to the UNITAID Executive Board in Dec-2009. The categories of savings in Section A of this analysis are consistent with those in the original MPP document to allow for a side-by-side comparison. For each category, we have provided an explanation of our methodology and how it differs from that of the MPP. While all calculations in Section A are based on a hypothetical MPP deal, Section B of this document discusses the financial impact of the actual deal that MPP has recently negotiated with Gilead.

A. Potential Financial Impact of MPP

(1) Reduced transaction costs for FDCs

The MPP estimated one-time savings of $195,000 that could result from their involvement in negotiating voluntary licenses (VLs) for the components of an FDC between 3 originators and 5 generic companies. These savings are based on the assumption that in the absence of MPP, these organizations would need to negotiate 15 separate bilateral agreements, whereas with MPP only need 8 agreements are needed.

I-MAK/ITPC does not dispute MPP's logic and methodology. We agree that this level of savings is possible in the hypothetical scenario that MPP has described. However, this should be considered a high-end estimate as this scenario has higher savings potential than other possible scenarios (e.g. if 1 or more of the components of the FDC are unpatented and don't require licenses).

	MPP analysis	*I-MAK/ITPC analysis*
TOTAL SAVINGS (one-time)	$0.2M	$0.2M

(2) FDC discount

The MPP estimated total 5-year savings of $27.7M (or $5.5M/year on average) that could result from enabling the development of lower-cost FDCs through negotiating generic VLs. This is based on historical price data for the d4T/3TC/NVP FDC vs. single formulations. MPP also calculated this using AZT/3TC/NVP as the comparison product, which yields a lower level of savings ($10.9M over 5 years).

I-MAK/ITPC does not agree with the basic premise that MPP will enable FDC development. In the absence of MPP, such products could still be developed through direct VLs or other existing mechanisms for overcoming IP barriers [1]. Such mechanisms have successfully enabled generic competition across all WHO-recommended ARVs to date. While MPP can facilitate the process of voluntary licensing, companies willing to issue VLs would be able to do so without MPP.

However, given that MPP can *streamline* the VL process, we believe they could reasonably *accelerate* the development of a generic FDC by approximately 6 months. Therefore, using MPP's savings calculations averaged between the D4T and AZT scenarios, we calculate potential one-time savings of $1.9M. This is equal to the average half-year savings over the 5-year timeframe of MPP's analysis.

	MPP analysis	***I-MAK/ITPC analysis***
TOTAL SAVINGS	$5.5M (annual)	$1.9M (one-time)

(3) "Newer" Medicines

The MPP estimated average annual savings of $1.23B/year or $34.6M/year for new medicines (depending on whether or not the originator offers tiered pricing). These savings are based on the premise that MPP will enable generic competition for such medicines, and assumes that prices would behave analogous to TDF 300mg prices over time.

I-MAK/ITPC does not agree with MPP's methodology. In the absence of MPP, generic competition for new ARVs would still be possible through existing mechanisms as discussed above. Further, it is misleading to calculate savings based on the price of TDF, as TDF prices have dropped significantly over time due to a combination of generic competition and process chemistry & sourcing improvements.

We have therefore calculated potential savings based on the assumption that MPP could *accelerate* generic market entry by 6-months using the same logic as above. Patient volume assumptions are consistent with MPP's analysis, and price assumptions are based on the difference in price between originator and generic versions of AZT in the first 5 years after generic market entry[2].

	MPP analysis	***I-MAK/ITPC analysis***
TOTAL SAVINGS	$34.6M-$1.2B (annual)	$16.9M (one-time)

[1] Compulsory licenses or use of other flexibilities in patent laws.
[2] Source: "Untangling the Web of Antiretroviral Price Reductions," MSF.

(4) Pediatric Solids vs. Liquids

Similar to categories 2 and 3 above, the MPP has estimated total savings of $41.4M over 5 years (or $8.3M/year) assuming they enable the development of solid pediatric formulations, and specifically FDCs, versus more expensive liquid formulations developed by originators. Again, we believe such formulations would be developed in the absence of MPP, and that MPP could only potentially accelerate their development by ~6 months. We therefore estimate a potential one-time savings of $4.1M based on the average half-year savings over the 5-year timeframe of MPP's analysis.

	MPP analysis	*I-MAK/ITPC analysis*
TOTAL SAVINGS	$8.3M (annual)	$4.1M (one-time)

(5) Expanded vs. Limited Voluntary Licensing

The MPP has assumed total savings of $18M over 5 years (or $3.6M/year) based upon the assumption that they will enable widespread voluntary licensing and therefore robust generic competition, leading to lower prices than would be seen with limited VLs.

I-MAK/ITPC disagrees with the notion that MPP "enables" widespread licensing. An originator company is either willing to issue widespread VLs or not, regardless of MPP. There is also no reason to believe that a company would only issue limited licenses on its own but license broadly under MPP.

Therefore, I-MAK/ITPC rejects the validity of estimated savings in this area.

	MPP analysis	*I-MAK/ITPC analysis*
TOTAL SAVINGS	$3.6M (annual)	$0M

Summary of Total Economic Benefits ($M)

Source	MPP analysis	I-MAK/ITPC analysis
1. Reduced transaction costs	0.2 *(one-time)*	0.2 *(one-time)*
2. FDC discount	5.5 *(annual)*	1.9 *(one-time)*
3. New medicine	34.6-1,230 *(annual)*	16.9 *(one-time)*
4. Pediatric formulation (solid FDC)	8.3 *(annual)*	4.1 *(one-time)*
5. Widespread voluntary licensing	3.6 *(annual)*	0
Total Savings	**$52M / year** (low end estimate)	**$23M (one-time)** (high end estimate)

B. Estimated Financial Impact of Recent MPP-Gilead Deal

MPP has recently completed its first major deal with an originator, Gilead, which covers TDF and 2 new drugs in development (Cobicistat and Elvitegravir). This section analyzes the financial impact of this deal on the market for TDF. Impact for the 2 new products cannot be analyzed, as it has not been established that these 2 products will be superior to alternatives in terms of clinical efficacy, cost, and/or side effects. Until such facts are established, it is not possible to determine whether these products will be relevant for public health programs in developing countries.

Against the savings categories mentioned in Section A, we do not expect the MPP-Gilead license for TDF to generate any savings for the following reasons:

- **Reduced transaction costs:** Gilead had already negotiated 13 separate voluntary licenses directly with generic companies prior to signing a deal with MPP
- **FDC discount:** TDF-based FDCs are already being produced by generics
- **New medicine:** TDF is not a new medicine
- **Pediatric formulation:** TDF is not currently indicated for pediatric use
- **Widespread voluntary licensing:** Widespread VLs were already in place before MPP deal

Though no economic benefit will result from the MPP-Gilead license in these areas, the deal can be expected to produce savings from lower royalty rates.[3] Whereas previous generic VLs for TDF mandated 5% royalty payments to Gilead, the new MPP license has reduced the royalty rate to 3% for countries where there are no patents on TDF. (If patents are granted, the royalties for affected countries would return to 5%.)

Assuming that TDF remains unpatented in India and most developing countries, we estimate that this deal can generate savings of $20.1M over the next 5 years, or **$4.0M/year** on average. This calculation is based on projected TDF volumes and prices over the next 5 years and assumes that 85% of total TDF volumes would be supplied under generic voluntary licenses (with the originator capturing 5% and unlicensed generics, e.g. Cipla, capturing 10%). This should be considered a high-end estimate of savings, as a lower level of savings would be realized in the event that Gilead and unlicensed generics capture greater than 15% combined market share, or that TDF is patented in India and therefore royalty rates return to 5%.

[3] Expected savings are based on a sub-licensee signing the MPP license. As of 2 October 2011, no generic companies had signed on.