VOLUNTARY LICENSING

RIGHT FOR HEALTH SMART FOR BUSINESS

medicines patent pool

How voluntary licensing advances global health while being economically viable for biopharmaceutical companies.[1]

Access the report

SEPTEMBER 2024

ABOUT THE REPORT

The Medicines Patent Pool (MPP) partnered with the Boston Consulting Group (BCG) to conduct this study aimed at demonstrating the value of voluntary licensing. Research was conducted using quantitative and qualitative data. The quantitative data used for the analyses was collected from IQVIA and from the MPP database.

8 KEY DRIVERS FOR VALUE [2]

Why is voluntary licensing interesting for biopharma companies?

Core benefits

1. The non-originator market represents between **6%-28% of product sales in low- and middle-income countries**
2. These sales could unlock between **2%-17% of additional revenue** for biopharmaceutical companies from splitting margins with non-originators
3. Non-originator sales reach **4 times more patients** than originator sales
4. Developing countries have market shaping capabilities: **up to 4 times more growth** for follow-up drugs in pre-shaped markets
5. Non-originators sales do not cannibalise originator sales, they allow to **reach new patient segments**

The benefits of voluntary licensing when done with the right partner

Avoided costs

6. MPP's hands–on licence management model can help mitigate product diversion. Product diversion can lead to yearly revenue loss per country estimated to range between USD 2 million and USD 8 million
7. **USD 10 million across 22 countries** avoided in operational costs through partnering with MPP

The benefits of voluntary licensing as a health equity strategy

Secondary benefits

8. **USD 7 million - USD 50 million in HR costs** avoided per year depending on company size, through lower attrition and higher employee engagement

1. Biopharmaceutical companies include all pharmaceutical companies focusing on the research, development and production of both biologic drugs and the more traditional chemically synthesized molecules.
2. The 8 drivers outlined in this document are part of a comprehensive analysis and should not be interpreted in isolation. To fully understand the context and implications of these drivers, readers are encouraged to access the full report (see QR code above).

EXECUTIVE SUMMARY OF THE REPORT

Voluntary licensing is one of several approaches that has been proven to help expand access to medicines. **If done in the right conditions, use of voluntary licensing for medicines and vaccines could increase patient reach for biopharmaceutical companies and could contribute to reducing global health inequalities, while being economically viable.**

THERE IS AN OPPORTUNITY FOR VOLUNTARY LICENSING ON NCDs

While many of the highest-profile voluntary licences have been for infectious diseases such as HIV and the hepatitis C virus (HCV), as well as the COVID-19, **there is an opportunity for voluntary licensing within non-communicable diseases (NCDs).** NCDs account for 74% of all deaths globally, 77% of which are in low- and middle-income countries and include mainly diabetes, cancer, and cardiovascular and respiratory diseases. These are explored in the analysis of this report.

REPRESENTING COMMERCIAL BENEFITS FOR ORIGINATORS

There exists a market for both originator and non-originator product sales in low- and middle-income countries. Indeed, non-originator sales of molecules treating diabetes, cancer and cardiovascular diseases across 22 lower-middle income countries and upper-middle income countries represent **between 6% and 28% of market share in value** depending on the therapeutic area.

Contracting licensing agreements can allow originators to leverage manufacturers' margin levels in upper-middle income countries and open revenue streams by negotiating margin splits. Therefore, voluntary licensing could unlock between **2% and 17% of additional revenue for originators** in upper-middle income countries.

AND ENABLING TO INCREASE PATIENT REACH

As a whole, non-originator products treating diabetes, oncology, and cardiovascular diseases **reach four times more patients** than originator products do across 22 lower-middle income countries and upper-middle income countries.

Increasing patient reach and patient diversity with voluntary licensing could allow data collection on a larger patient base, **strengthening Real-World Evidence (RWE) corpus on a licensed product.**

HEALTH EQUITY STRATEGIES HAVE AN IMPACT ON EMPLOYEE RETENTION AND COST OF BORROWING FOR ORIGINATORS

Health equity strategies such as voluntary licensing increase talent attraction and retention and therefore can reduce attrition rates by 1%. This 1% reduction in attrition rate is estimated to **save biopharmaceutical companies** from USD 7 million to USD 50 million depending on company size, training time and average salaries.

Strategies such as voluntary licensing that improve access to healthcare products for priority diseases and in priority countries represent sustainability targets that allow biopharmaceutical companies to issue Sustainability Linked Bonds (SLBs). These bonds usually have low interest rates and contribute to reducing biopharmaceutical companies' cost of borrowing.

THE BENEFITS OF LICENSING VIA MPP

Voluntary licences can be contracted bilaterally between companies and/or via MPP. Both options require a high level of trust, partnership, and investment by both the originator and recipient parties, meaning that they can only be on mutually agreed terms.

MPP's hands-on licence management model can help mitigate product diversion (the unauthorised sales of products outside of the originator's intended geography or intended distribution channels) through (i) trustworthy collaborations with partners; (ii) strict licensee selection processes; (iii) approval requirements from Stringent Regulatory Authorities prior to and in addition of the needed regulatory approval in each individual country; (iv) post-market surveillance mechanisms; (v) stringent trade dress requirements; and (vi) strong legal frameworks.

MPP's approach to mitigate product diversion can prevent originators from **yearly revenue loss estimated to range between USD 2 million per lower-middle income country and USD 8 million per upper-middle income country.**

Annual operational costs associated with bilateral agreements are estimated to reach USD 10 million in consultancies and partnership management fees to license one product in 22 lower-middle income countries and upper-middle income countries. These licence management costs are completely avoided with MPP as a partner.

VOLUNTARY LICENSING, AN ACCESS STRATEGY AMONG OTHERS

Finally, it should be recognised that voluntary licensing alone is not sufficient to ensure patient access to medicines – healthcare system capability to diagnose patients and deliver treatments are critical, together with other key capabilities along the regulatory and supply chains, including raw materials sourcing, cold chains, tariffs, and export restrictions. Finally, political commitment and government funding to invest in health are key to enabling access to medicines.

OUR IMPACT

The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organisations, industry, patient groups, and other stakeholders to prioritise and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. MPP negotiates licensing agreements with innovator pharmaceutical companies that will enable more affordable, quality-assured versions of priority new treatments to reach LMICs sooner.

148 countries have benefited from access to MPP's products

43.56 billion doses of treatment supplied (Jan 2012 - Dec 2023)

US$1.9 billion dollars saved through MPP's licences (Jan 2012 - Dec 2023)

22 patent holders with MPP signed agreements

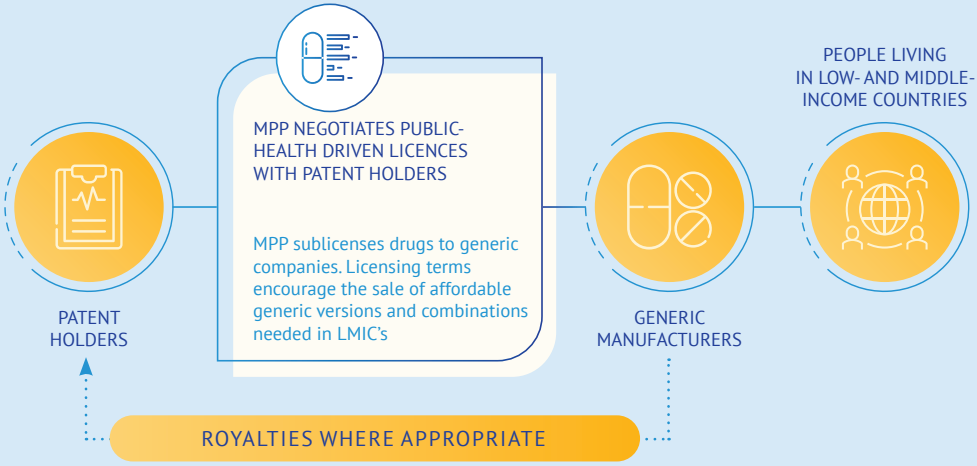
57 generic manufacturers and product developers have sublicences from MPP

By 2030

170,000 deaths averted

US$3.9 billion projected dollars saved

THE MPP MODEL – HOW WE WORK



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Disclaimer: The views expressed in this report are those of the authors and not of the funders or Advisory Board members.

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