



A Checklist for Voluntary Licensing of pharmaceutical drugs

Outline and purpose of the document: This Checklist for Voluntary Licensing is part of the IMPACT3T IP 'Crisis Scenario' tool-kit. It is designed to help the owners of intellectual property rights (IPR) to engage more confidently in voluntary licensing in times of crisis or emergency.

Target readership: This document is aimed at technology transfer offices (TTOS), enterprises and licensing professionals who may be setting up and assisting in a rapid voluntary license to respond quickly to an external emergency including engaging with the MPP (Medicines Patent Pool).

Level: This document assumes that the reader has familiarity with Intellectual Property Rights (IPR) and in particular patent regulations and has previously been involved in negotiating an IPR licensing contract. If the organisation has no prior experience with technology licensing then seeking external professional help is advised.

Focus: The focus of this document is medical pharmaceutical products and APIs (Active Pharmaceutical Ingredient). For those seeking to license medical devices e.g. ventilators, the reader is invited to review the IMPACT3T IP documents relating to **Open Source licensing**.

Sources of information: This document is based strongly on the **Report of the Task Force on Voluntary Licensing and Access to Medicines** produced by a team under the Global Access in Action initiative, Version 1.1 April 22, 2023¹ See <https://globalaccessaction.org/vlam/> This report was based strongly on licenses agreed with the MPP that are automatically placed in the public domain. See <https://medicinespatentpool.org/progress-achievements/licences>

Additional comment and references have been added by the IMPACT3T IP team.

Scope: The 11 Good Practice Recommendations draw on a record of successful deployments of VLs and as such are grounded in a substantial body of Customary Practice (CP). For further recommendations related to VL that require stronger involvement of stakeholders including governments and donor agencies, the reader is invited to consult the analysis and recommendations of the original report.

Disclaimer: This check-list is not designed to be exhaustive. It is intended purely to provide an overview of the kind of issues that may need to be considered when formulating a voluntary licensing agreement. The authors, IMPACT3T IP and project partners can accept no responsibility for the outcomes and results of its use. It should not be regarded as an alternative to seeking qualified professional licensing support.

¹ See <https://globalaccessaction.org/vlam/>



Acronyms

API	Active Pharmaceutical Ingredient
EMA	European Medicines Agency
FDA	Federal Drug Approval
MHRA	Medicines and Healthcare products Regulatory Agency
MPP	Medicines Patent Pool
LMIC	Lower and Middle Income Countries
SRA	Stringent Regulatory Authority
VL	Voluntary Licensing



Key issues in Voluntary Licensing agreements and recommendations for addressing each one.

Below is a list of the main issues that must be addressed in a technology licensing agreement through legal clauses and the use of **Customary Practice** when formulating these clauses for a VL. A recommended **Good Practice** approach to each one in a VL is laid out. Foot-notes have been used to offer further illustrative examples. These draw strongly on published VL agreements made via the MPP (Medicines Patent Pool) available at: <https://medicinespatentpool.org/progress-achievements/licences>. Extended text is to be found in the Annex with a link to the online agreements.

1. 'Purpose' of the license

Customary Practice: VLs routinely state that their **Purpose** is to increase access to certain products and APIs (Active Pharmaceutical Ingredient) to satisfy unmet medical needs in the covered territory. The license requires terms and conditions consistent with that objective (e.g. price, non-diversion, marketing etc).² Some VLs also prohibit the licensees from engaging in any activity inconsistent with the purpose of increasing access.³

Good Practice Recommendation: *All VLs should make their access-enhancing purpose explicit. In addition, VLs should provide for the case wherein if any of their provisions are subsequently deemed ambiguous, they should be interpreted in a fashion that would promote that objective.*

2. Parties

Customary Practice: The Licensor is invariably the owner of the IP and know-how rights that are transferred. The Licensee is typically a pharmaceutical or medical devices company. Other partners that may be involved include specialised technology pools such as the MPP which is authorized to license the rights conveyed to sub-licensees on the terms specified.

In addition, successful VLs require attention to be paid to the interests of other stakeholders, including LMIC (Lower and Middle Income Countries) governments, funders, multilateral organizations, civil-society organizations, and distributors.

Good Practice Recommendation: *Licensor and licensee should agree to cooperate in encouraging such other stakeholders to partner in helping to improve health care infrastructure in the territory covered by the license.*

3. Rights Transferred

Customary Practice: Typically, the Licensor conveys the right to use specific IP or know-how to manufacture and/or sell specified products and related APIs in particular territories. The countries covered and the status of the patents involved are often listed in appendices.⁴ Typically, the license is non-exclusive, non-sub-licensable (or with limited sublicensing rights requiring notice to Licensor, audits, and assumption of liability) and non-transferrable (except to affiliates)⁵. Transfers of specified products are sometimes preconditioned on their regulatory approval by a SRA (Stringent Regulatory Authority (SRA) e.g. European Medicines Agency (EMA) in the EU, the MHRA in the UK and the FDA in the USA.

² E.g. The **Merck-MPP License 2021** states that this agreement is intended to increase "access to quality, safe, efficacious and affordable medications..." See <https://medicinespatentpool.org/licence-post/molnupiravir-mol>
The "Whereas" clauses of the **Gilead Hepatitis C (HCV) License** state that Licensor and Licensee wish "to facilitate access". See <https://www.gilead.com/-/media/gileadcorpdesign/pdf/responsibility/global-health-and-access/access-in-low--and-middle-income-countries/access-partnerships/2017-amended--restated-voluntary-hcv-license-agreement-pdf.pdf>

³ MPP's MSD sublicense allows MPP to terminate after notice and a cure period if it concludes its sub-licensee is failing to promote access. Para. 10.4.

⁴ See for example Gilead HCV License, Appendix. 1&2.

⁵ See for example Gilead HCV License, Para. 3.4.



Licenses to the MPP convey the right to sublicense the rights transferred and to sell outside the licensed territory for authorized uses including sales by public authorities.⁶ Sales through third parties are controlled to ensure Licensor approval of the parties and compliance by them of all terms of the license. The transfer may be deemed “one time.”

Good Practice Recommendation: *A VL should include assurances by the Licensor to provide useful know-how to Licensees, including training where necessary. Licensees should be empowered to sell into additional territories upon establishing the need for increased access in such areas and Licensee’s capacity to perform.*

4. Quality Standards

Customary Practice: In a VL, Licensees are free to source API from any authorized source they choose, and to sell API royalty-free to each other. That API is then used by the licensee to manufacture the finished product. For example, Gilead required Licensees to obtain WHO Prequalification and/or Tentative FDA Approval to ensure acceptable quality standards are met. However, this is not necessarily an industry standard practice for producers of generic medicines.

Good Practice Recommendation: *In order to ensure quality standards, Licensees should be required to seek approval via a SRA (e.g., WHO Prequalification, Tentative FDA approval if applicable, or European Medical Agency (EMA) or equivalent).*

5. Sales and Marketing

Customary Practice: Typical provisions pertaining to the sale and marketing of products authorized by a VL include⁷: all statements by Licensees related to products based on the license must be accurate; any reference to the Licensor on or associated with the products sold must be approved by the Licensor in writing; all products sold must indicate they are made pursuant to a license from Licensor; distinct trade names and trade dress may be required; Licensee must terminate any third-party seller that fails to abide by the terms of the license.

Good Practice Recommendation: *The Licensor should maintain oversight of key aspects of sales and marketing behaviour and the use of trademarks by Licensees, both to protect the Licensor’s reputation and to protect the reputation of the licensing regime.*

6. Compliance with Laws

Customary Practice: A VL typically provides that the Licensee must comply at its own expense with all applicable laws and regulations, including the procedures for obtaining regulatory approval and all safety related reports. Licensee must also comply with bribery/corruption statutes, and Licensor is not responsible for Licensee misconduct.


Good Practice Recommendation: *Such obligations are sound but should be supplemented by a commitment by the Licensor to assist the Licensee in obtaining regulatory approvals (e.g., timely submission of product dossier to WHO for prequalification review or to an SRA).*

7. Liability

Customary Practice: The Licensee typically indemnifies the Licensor for damages caused by Licensee’s performance. Licenses exclude liability of Licensor for any form of “Special Damages (including exemplary, punitive, loss of profits, etc.).” Licensee typically is responsible for claims by third parties based on Licensee’s conduct but must get Licensor’s written consent to any settlement

⁶ MPP MSD License, Para. 2.3.

⁷ See, e.g., Gilead 2006 Tenofovir License, Para. 2.4(e)



by Licensee of such claims. Licensees may be required to obtain insurance to cover claims for products made or sold.⁸

Good Practice Recommendation: *Provisions of these sorts designed to ensure that the Licensee bears financial responsibility for the Licensee's misconduct are sound. In addition, a VL should specify the kinds of misconduct that will constitute grounds for terminating the License.*

8. Termination

Customary Practice: Termination is allowed by either party with a notice and redress/cure period (e.g., 30 days) for material breaches of material terms. Licensor may be allowed to terminate immediately where in good faith it concludes control of the Licensee has changed or specified breaches have occurred, such as diversion, inadequate quality, using APIs from unauthorized sources, non-payment of royalties, insolvency, etc. Licensees may be given a specified period to establish that the conditions cited by Licensor do not exist. Licensor or Licensee rights under the license may be deemed to survive in specified circumstances, as where investments have been made. Licensee may be given the right to terminate its use of licensed APIs or patents after a specified period.

Good Practice Recommendation: *Provisions such as those outlined above are designed to protect the integrity of the licensing program.*

9. Confidentiality

Customary Practice: Licenses uniformly provide for the maintenance of confidentiality of all information shared on that basis. Information publicly available may not be deemed confidential, and the obligation to maintain confidentiality is inapplicable in the event a court or agency with appropriate authority concludes that the information should not be confidential.

Good Practice Recommendation: *The license should specify obligations regarding confidential information and whether confidentiality applies to any mediation and/or arbitration.*

10. Use of Names & Agency

Customary Practice: Parties of VLs typically agree not to use each other's names with such exceptions as they decide to make. The parties are deemed to be independent contractors with no authority to bind each other except by written agreement.

Good Practice Recommendation: *Licenses should include such provisions as they enable parties to protect their interests with minimum reliance on IP rights and litigation.*

11. Dispute Resolution

Customary Practice: VLs typically specify the jurisdiction whose laws will govern any dispute between Licensor and Licensee. Most VLs provide for arbitration of all disputes, after an effort to mediate. Some specify the terms and provider of arbitration services (e.g., number of arbitrators, applicable rules, deadlines). With respect to litigation, VLs sometimes specify the court that shall have jurisdiction.

Good Practice Recommendation: *A VL should provide such guidance for resolving any disputes. In addition, a VL can provide for fee shifting in general or for specific violations (e.g., in the event of unauthorized or improper use of the IP transferred).*

⁸ See Gilead, Original 2006 Tenofovir HIV License Para. 9 (no less than \$1 million per year). See <https://www.gilead.com/-/media/gileadcorpdesign/pdf/responsibility/global-health-and-access/access-in-low--and-middle-income-countries/access-partnerships/2006-original-hiv-voluntary-license-agreement-pdf.pdf>



Annexe 1. Published VL licenses

The following VL agreements have been used to illustrate the main points:

1. Merck-MPP License 2021

- MSD MPP HoA executed
- MSD MMP Sublicense
- MSD MPP HoA Ammendment

Available at: <https://medicinespatentpool.org/licence-post/molnupiravir-mol>

2. Gilead Hepatitis C (HCV) License Amended and reinstated 2017

Available at: <https://www.gilead.com/-/media/gileadcorpredesign/pdf/responsibility/global-health-and-access/access-in-low--and-middle-income-countries/access-partnerships/2017-amended--restated-voluntary-hcv-license-agreement-pdf.pdf>

3. Gilead HIV (Original 2006) Tenofovir (HIV) License

Available at: <https://www.gilead.com/-/media/gileadcorpredesign/pdf/responsibility/global-health-and-access/access-in-low--and-middle-income-countries/access-partnerships/2006-original-hiv-voluntary-license-agreement-pdf.pdf>