European Vaccine Initiative

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EVI Equitable Access Policy

EVI is committed to develop and deliver safe, efficacious, and affordable vaccines for global health to people in low- and middle-income countries (LMIC). As a non-profit organisation that contributes to solving global health inequalities, our work is focused on ensuring equitable and affordable access to the vaccines that we develop. We have therefore established a set of principles that guides our approach to access – from the design of target product profiles, intellectual property and licensing, data and results sharing, partnerships and collaborations, to local in-country advocacy and implementation activities.

The focus of EVI's product development activities has always focused on early- and middle stages of vaccine development from late pre-clinical to early clinical efficacy testing (phase II)). EVI's direct involvement in in-country implementation is therefore relatively limited compared to our core research and development (R&D) activities. Other organisations such as vaccine manufacturers, international vaccine procurers (e.g., GAVI and UNICEF) and local distributors (e.g., national ministries of Health) are typically much better equipped for in-country implementation activities. EVI is therefore playing a relatively passive role with respect to downstream implementation, although EVI will provide as much support as possible and relevant to the implementing organisations. EVI is nevertheless aware that decisions and directions taken during product development can dramatically impact the uptake and roll-out of licensed vaccines. This access policy provides high-level guidance on aspects related to access that should be considered during product development and when initiating collaboration with development partners.

1. Intellectual Property Rights, Ownership, and Freedom to Operate

Intellectual property rights (IPR) can be an important catalyst for biomedical innovation. When used indiscriminately, however, it can also create roadblocks for further product development, limit the possibility of new collaboration, limit follow-on R&D, or hinder affordable and equitable access of products to end-users.

To address these barriers, EVI applies two guiding principles to inform all contract negotiations around IPR and ownership:

- Vaccines for global health are affordable and accessible in an equitable manner to patients who need them; and
- Data and results from research in global health vaccines should be considered as global public goods whenever possible.

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EVI will not accept projects, where IPR is going to be an insurmountable barrier for EVI to 1) provide equitable and affordable access to end-product and/or 2) follow- up research and product development by EVI or on behalf of EVI.
EVI will enforce these principles further by requesting, whenever possible, relevant and adapted to the specific cases:

- Irrevocable, royalty-free, non-exclusive, transferable licenses in the contractually defined target disease(s);
- worldwide research and manufacturing rights to enable technology transfer and potential production at multiple, independent sites in order to increase production and decrease price of product.

The wording and concrete implementation of the principles above will depend on the specific context for each vaccine candidate and the associated product development collaboration. As an example, however, the phrasing below can be used in EVI's collaboration agreements:

"Should [*the party owning the intellectual property*] decide to abandon the further development of the vaccine candidate or should the timeframe for the development activities become disproportionately extended, EVI will then be granted a transferable, non-exclusive, and irrevocable commercial and research license. Such license shall be royalty free and shall be granted without any further action required or needed from the party owning the intellectual property, including clinical trials data arising from the conduct of the project. The license shall only be granted to make use of the intellectual property rights to ensure that the investigational vaccine or its subsequent modifications and/or combination vaccine products shall reach end-users in LMIC (according to UN classification). The license shall be granted exclusively to develop and deliver the investigational vaccine for the prevention or treatment of [*specific target disease/pathogen/condition*] "

2. Equitable and Affordable access

EVI provides a mechanism for accelerated development of vaccines for global health. EVI's aims to develop, deliver, and distribute vaccines in LMICs at prices that are affordable to the populations or to public sector entities that procure on their behalf.

To ensure the affordability of vaccines developed by EVI, the following condition will generally be enforced in product development collaborations:

"The commercialising Party agrees to use all reasonable efforts to make the product available and affordable to those most in need in LMIC and to entities procuring vaccines on their behalf. Making a product "available" shall in this context mean manufacturing it in adequate amounts, if

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necessary, through sub-licensees, and delivering it to the end-users, including through distributors. The meaning of "affordable" in this context shall be a price that is lower, equal, or only marginally higher than Cost of Goods Sold (COGS) plus cost of delivery."
For vaccines with dual use, or for products that will be licensed and commercialised in both High-Income Countries (HIC) and LMIC, affordable product pricing may be further ensured via the application of the Regulation of the European Union for tiered pricing of pharmaceutical products (Regulation (EU) No. 2016/793 of the European Parliament and of the Council of 11 May 2016, regarding tiered priced products).

3. Community Involvement and Benefit Sharing of Research Results

EVI is actively pursuing a principle of open and free access to all research data and research results from its activities, pursuant to EVI's "Data Sharing and Communication Policy".
Benefit sharing shall also mean that products resulting from EVI's activities shall first be made available to populations that need them most. This will be done with the intention that any product will be made available in a manner (including price considerations) that facilitates its widespread use in disease-endemic areas of LMIC countries.
EVI subscribes whole-heartedly to the GLOBAL CODE OF CONDUCT FOR RESEARCH IN RESOURCE-POOR SETTINGS (https://www.globalcodeofconduct.org/) and will adhere to its principles for equitable research partnerships and benefit sharing. In EVI's activities, a particular emphasis will therefore be put on concrete benefit sharing with populations and communities in LMIC that participates or contributes to EVI's research activities.

4. Implementation of the policy

All rights and obligations with respect to intellectual property, equitable and affordable access, and benefit sharing should be defined and clarified with collaborators, project partners and contractors at the earliest possible timepoint to avoid any misunderstandings or divergence of purpose.
The content of the current policy should therefore to the largest possible extent be reflected in the legal framework surrounding EVI's activities and collaboration with external parties such as Consortium Agreements, Collaboration Agreements, Investment Agreements, Sub-contracts, Patent Agreements, Licensing Agreements, Data Access Agreements, Exploitation plans and similar.
It is nevertheless acknowledged that EVI in some cases, particularly with respect to Grant Agreements, Investor Agreements, Contracts, and similar legal documents from funding authorities may not be able to modify or influence the content of the documents. In such situations, EVI will on a case-by-case basis evaluate whether EVI's integrity in any way is

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compromised, or whether the fixed terms can be accepted and support the overall goals and mission of EVI.

5. Amendments and Changes to the Policy

EVI will review, revise and/or amend this policy or any of its terms at its discretion, at any time to make sure that its content reflects the highest ethical standards with respect to global access and benefit sharing. Amendments and changes to the policy can be introduced upon recommendation by the EVI Secretariat, represented by the Executive Director, and approval by the EVI General Assembly