Access Planning for the Future EU Research Framework in the Health Context

Comments of the Medicines Patent Pool to the European Commission Regarding Access Planning Obligations in FP10

Introduction

With a €95.5 billion budget, Horizon Europe, the current EU research framework, is one of the world's most ambitious public R&D programmes. A significant portion of this budget supports biomedical and health-related research. The Health Cluster (Cluster 1) of Horizon Europe allocates over €8.3 billion to health-related R&D over the 7-year period. The new research framework programme (FP10) of the European Union currently under negotiation for the period 2028-2035 is expected to substantially increase this funding.

FP10 presents an opportunity for the European Commission to adopt a forward-thinking funding policy that facilitates downstream access to technologies derived from Commission-funded inventions in low- and middle-income countries (LMICs) in ways that align with existing European policy commitments, such as in the EU Global Health Strategy. Such a policy could be accomplished through well-crafted access obligations, including a baseline nonprescriptive obligation on the recipients of funding to submit an access plan in the event that the funded research were to result in a registered health product specifying the ways in which the rights holder intends to address core issues of access for the products within LMICs, to the extent that product may be needed in LMICs.

An access-plan requirement prompts early consideration of the measures needed to ensure equitable, affordable, and timely access in LMICs while remaining flexible enough to preserve commercialization incentives and exit value for spinouts and small and medium enterprises (SMEs). Adoption of such an obligation in FP10 would align the European Commission with existing practice among major philanthropic and other global health funders that already include access and intellectual property management expectations (*e.g.*, Gates Foundation, Wellcome Trust, Unitaid), with developments by other major public funders, and with emerging public policies promoting equitable access.

Public Health Rationale for Access Planning Requirements

While an access planning obligation may have utility outside of the health context, it is a particularly important approach to funding in the health sphere. Public funding, typically financed by taxpayers and public budgets, frequently supports early-stage discovery of medical technologies. And yet without planning for downstream barriers to affordable access that may and frequently do arise in LMICs, many funded discoveries in the health sphere often become available in LMICs many years after introduction in high-income countries (HICs) and frequently with insufficient attention to affordability or sustainability, if the technologies become available in LMICs at all. The severe disparities of access often lead to worse health outcomes in LMICs across a wide variety of disease fields. Requiring an access plan drives early consideration of those downstream barriers, increasing the

probability that publicly funded innovations reach patients who need them across income settings where market incentives alone may not produce timely availability or affordable supply.

Access plan requirements can also be an important method for funders and governments to manage and reduce political, reputational, and programmatic risks that may arise through access failures (*e.g.,* supply shortages, price controversies, *etc.*). Public funders face growing scrutiny over whether their investments yield public value and do not worsen existing inequities, and FP10 will likely have increased pressure from Member States and civil society for accountability and transparency in how public funds translate into societal benefits both within the EU and globally. Access planning serves as a low-cost, high-impact risk mitigation tool ensuring early awareness of potential access barriers, reduces the likelihood of political backlash or post hoc disputes over pricing or IP, and strengthens public trust in the research and innovation system by showing that the EU expects visibility into commercialization strategies in order to better overcome potential downstream barriers to impact.

Alignment with recent developments in EU/global policy and with existing practice by other global health funders and research institutions

EU policy positions

By adopting an access plan obligation, the Commission would align FP10 with a variety of existing commitments and solidify the EU's global leadership in equitable research governance.

The Sustainable Development Goals (SDGs) and the 2030 Agenda for Sustainable Development were adopted by all Members of the United Nations in 2015, with Goal 3 being to "Ensure healthy lives and promote well-being for all at all ages," and emphasizing the importance of access to medical technologies as critical to the achievement of SDG 3.

The European Commission has additionally already made high-level commitments to equitable access to health technologies, including the EU Global Health Strategy (2022), which explicitly calls for "affordable and equitable access" to medical countermeasures, and enhancing "EU finance for global health with maximum impact." The EU has supported the WHO Pandemic Agreement which emphasizes access as a core principle, and the Horizon Europe Model Grant Agreement already gestures in the direction of access by embedding principles of open science and data sharing; adding access-oriented planning to the grant language would be a logical reflection of EU policy.

Other governments are moving towards equitable access obligations for publicly funded research.

Other major public funders are embracing equitable access to publicly funded research in their policy frameworks, in various ways.

Spain. In Spain, the Pharmaceutical Strategy 2024-2028 contains access and research and development among its pillars, and one of six key priority actions is to promote the interaction in research and development between the public and private sectors. In this action, the strategy commits to developing access guidelines that help developers who receive public funding towards access models with a return on social investment.

The Netherlands. In the Netherlands, the National Federation (NFU) of University Medical Centers (UMCs), at the request of the Ministry of Health, Welfare and Sport, issued Ten Principles for Socially Responsible Licensing and a toolkit to assist universities in following through on these principles. The principles are intended to ensure that intellectual property developed at the university medical centers benefits society and specifically includes focus on the role that a university can play in ensuring market access or development (where possible), and on ensuring that a licensee does not thwart affordable access in lower resource settings.

United States. In the United States, the National Institutes of Health recently introduced its Intramural Research Program Access Planning Policy with detailed guidance articulating a waivable obligation on NIH licensees to submit an access plan outlining steps intended to promote patient access to the licensed products where the licensee is intending to commercialize drugs, biologics (including vaccines), or devices for the prevention, diagnosis, or treatment of human disease. Once approved, these access plans are incorporated into the licence agreement. The guidance specifies that the access plans are assessed across criteria of affordability, availability, acceptability, and sustainability, and plans are expected to be updated over the course of product development. The policy is focused primarily on broad access to a licensed product for the U.S. population, but "can include, as applicable, strategies through the lens of promoting equitable access … for populations in low- and lower-middle-income countries, as defined using the World Bank classification system." Assessment of the plans by NIH will consider the relevant contributions of the parties "…and the relative contributions of the public and private sector to the product's ultimate development."

The policy affords significant latitude to the licensee in terms of appropriate strategies to ensure patient access, but partnerships are envisioned as being core to a flexible approach, and the guidance document sets forth a lengthy non-exhaustive list of strategies and potential types of partnerships across the development and commercialization of a medical technology, including, for example, engaging with product development partnerships, collaborating with ministries of health or community organizations, and licensing to access-oriented institutions.

Major global health funders have long utilized a variety of access conditions in their funding agreements.

Other major funders such as the Gates Foundation, Wellcome Trust, and Unitaid have long been leaders in incorporating equitable access conditions into their funding agreements as

a way to ensure that the access policies and specific objectives of each are satisfied. While each funder operates in its own way and focuses on its own specific strategic goals – Unitaid primarily using catalytic funding for late-stage product development and market entry for medical technologies within Unitaid's mandate (HIV, tuberculosis, malaria, maternal and child health); Wellcome Trust with a broad portfolio across sectors, types of technology, stage of development and public health needs; and Gates Foundation in spurring innovation and disruptive change through strategic, high-impact investment – each seeks to achieve impact and equitable outcomes through a variety of access-oriented obligations in their funding agreements. These may include, for example, specific provisions on the following:

- Affordable pricing (cost+ or target pricing)
- Registration commitments ensuring in-country registration
- Supply commitments to ensure adequate volumes and timely supply
- Quality Assurance (stringent regulatory approval, WHO Listed Authority)
- Intellectual Property management (*e.g.,* licensing to the Medicines Patent Pool)
- Acceptability
- Step-in rights and/or humanitarian licences

The three funders each have noted that, as with the non-prescriptive access-planning approach, there is typically a need to maintain flexibility in their approach rather than adopt a one-size-fits-all standard, as technologies, public health needs, and commercial considerations will vary.

Universities and other research institutions are increasingly willing to incorporate an access-planning provision into their exclusive licences for early-stage medical technologies.

In 2020, the Medicines Patent Pool was invited by the University of California Los Angeles (UCLA) Technology Development Group (TDG) to develop a workable clause that would meaningfully improve the university's exclusive licensing template for early-stage medical technologies with regard to affordable access in low- and middle- income countries (LMICs), with the important proviso that the clause should be amenable to a variety of stakeholders. This clause has subsequently gone on to be adopted or piloted by over twenty universities and research institutions in Europe and North America.

The MPP/UCLA collaboration yielded an affordable access plan provision that:

- Requires licensees to
    - submit a plan of how they will achieve affordable access for the licensed product(s) in low- and middle-income countries, with strategies and timelines; and
    - identify countries in which the licensee has no intention of commercializing
- Only requires the submission of the plan when it is reasonably certain that the licensed product will be commercialised – *i.e.*, within a specified amount of time of

having received regulatory approval, which allows the licensee to focus energy and resources on the critical research and development activities needed to advance a technology and only develop the plan if/when the product is ready for market launch.

- Allows the licensor to call upon a "designated entity" with relevant public health expertise to assist in conversations with the licensee regarding the access plan. This designated entity could be the Medicines Patent Pool, where appropriate, but could be any third party with the requisite expertise.

While drafting this clause, MPP and UCLA vetted this language with various stakeholders, including venture capital firms, IP law firms, civil society groups and others, and UCLA has used this provision in its exclusive biopharma licences since then without issue across a variety of disease fields. While most of the agreements are with private companies, several of the agreements with public corporations have been made available via the Securities and Exchange Commission, including one with Radiopharm Theranostics Limited for a monoclonal antibody, and one with Kalthera Inc. for a technology coming from the laboratory of a UCLA immunology researcher.

Since UCLA's first use of this provision, MPP has seen rapid uptake of this provision with universities and other research institutions in Europe and North America, including major research universities such as UC Berkeley, Columbia University, the University of Michigan, several of the Netherlands NFU UMCs, and others like the Barcelona Global Health Institute (ISGlobal), with many speaking publicly about their usage of the clause and stating that they have received little to no pushback on use of the clause. University of Michigan Innovation Partnerships, for example, has publicly stated that while their use of this affordable access plan provision initially prompted some straightforward questions from licensees about what the language meant and how it would work, subsequently the clause has been a nonissue and readily accepted by Michigan's most frequent startup law firms including one of the leading venture capital law firms, with inclusion in nine recent exclusive licences for therapeutics. This representative said that helpful talking points in their discussions have included: (1) explaining what the clause is (information sharing, collaboration) and what it isn't (prescriptive); (2) pointing to the fact that most large pharmaceutical companies have established access approaches; and (3) major U.S. research universities have been incorporating this clause without issue.

More information about this clause and MPP's work on upstream access is available on the MPP website.

Recommendations for the European Commission for Incorporating an Access Plan Obligation into FP10 Funding Agreements While Preserving Commercial Viability

Scope and Proportionality. While the NIH policy and the MPP-UCLA language differ in some important ways, including the timing of the access plan submission, whether the plan is to be "approved," possible enforcement mechanisms, *etc*., both try to reckon with the real-world industry considerations to avoid interrupting licensing and deterring investors or

prospective acquirers. The openness of the MPP-UCLA language meets universities where they frequently find themselves in terms of leverage, or lack thereof, for early-stage licences. But a major funder such as the European Commission would logically have far more leverage. The Commission could look to the NIH policy's intentions of scope and proportionality as a way to ensure that an access plan obligation be applied in ways reasonably connected to the funded research – considering, for example, how much of the research and development has been funded by the Commission (*cf.* private investment) and for what stages – and scale expectations by development stage.[1] Early-stage discovery should require planning and intentions; later-stage funding can require more detailed operational plans and be more prescriptive, with more specific requirements of various access-related commitments in LMICs, whether related to supply, registration, pricing, IP management, *etc*. This kind of graduated approach, differentiating by development stage, would additionally mirror some of what other major global health funders have described in their own access approaches. And as with the NIH policy, FP10 could provide clear guidance and examples broken down by type of product (*e.g.* therapeutics, biologics, diagnostics, devices) to minimize apprehension around uncertainty of expectations.

Nonprescriptive Approach to Access Planning. Both the NIH policy and the MPP-UCLA language afford the industry partner the decision of what strategy is the best approach, inherently recognizing that different contexts may require different solutions. There may be some technologies for which licensing to manufacturers based in LMICs may be very appropriate, but in other cases there may be other suitable approaches. The nonprescriptive nature affords industry partners control over the activities anticipated to achieve access and allows them to identify options that make sense for their company, and which may in fact yield opportunity for market expansion rather than financial loss. This could be through licensing but may also be through other types of partnerships with organisations that exist to improve affordable access in LMICs.

*Transparency***.** There are legitimate and important arguments in favor of transparency especially where public funding is involved. These arguments are often seen to be at odds with the commercial considerations for industry. Both the NIH policy and the MPP-UCLA language strike a balance in terms of expecting some degree of transparency while implicitly recognizing industry concerns regarding confidentiality. Both require that a non-confidential version of the plan be provided such that the non-confidential version could be made available to the public. Such a requirement of a non-confidential version will help ensure accountability to public taxpayers and insulate the funder from criticism.

[1] See Section A of the NIH Intramural Research Program Access Planning Policy Implementation Guidance, Notice No. NOT-OD-25-137 ("NIH will also consider the relevant contributions of the parties in evaluating an Access Plan. For example, NIH will consider the nature of its patented technology, how that technology factors into the licensed product, the scope of the license, and the relative contributions of the public and private sector to the product's ultimate development. NIH will work closely with licensees to monitor progress and modify approved Access Plans, when appropriate and in concert with the licensee, to support successful commercial development and implementation of access strategies."). https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-137.html

LMICs Should Be in the Scope. The issues of affordable access to many health technologies extends far beyond high income countries and should include all low- and middle-income countries – including upper-middle income countries– as defined by the World Bank. The European Commission could clearly require that, as with the MPP-UCLA language, an access plan cover *all* LMICs, while also making clear that it is understood that not every funded technology is going to be needed in all LMICs. There could be a clearly provided mechanism allowing the funding recipient to seek a waiver of the obligation in instances where an access plan is not needed.

Implementation Partners. As part of any move to incorporate an access planning obligation in funding agreements, the European Commission could create a roster of implementation partners that would be willing to help translate access plans to reality. The Medicines Patent Pool would of course be willing to work closely with the European Commission, and to discuss its model of licensing and technology transfer with interested parties with no expectation that such modalities would be appropriate or viable in every instance. There would be many other access-oriented organizations and institutions around the world that would likely volunteer the same. The more work that the Commission can do to introduce access approaches to awardees, the easier planning for access should become. The Commission could additionally create a small roster of expert advisors who might be tasked with being a first line for answering awardee questions as may arise.

Conclusion

Incorporating an access planning requirement into FP10 funding would be an enormous step toward ensuing maximum impact for public investment while furthering EU policy goals on societal impact through equitable access and improving health outcomes in LMICs. Such a requirement would not require reinventing the wheel, and there is abundant expertise and experience to lean on as the European Commission considers such a policy. The Medicines Patent Pool is prepared to support the Commission to help make such a policy a success.