Unitaid
SAVE LIVES FASTER

Guidelines on equitable access

Designing programs and investments that support equitable access to health products

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Contents

1. Purpose of these guidelines on equitable access 4

2. How are Unitaid's access requirements secured? 6

3. When does Unitaid seek access commitments? 7

   a. **Direct financial support** 7

   b. **Technical support** 7

   c. **Supply side interventions** 7

4. What are Unitaid's access objectives? 9

5. What will access commitments look like in practice? 10

   a. **Affordability** 10

   b. **Availability** 13

   c. **Supply security** 14

   d. **Quality** 14

   e. **Demand and adoption** 14

6. Other considerations related to access 15

a. Management of intellectual property rights 15

b. Use of step-in rights 15

c. Use of equitable access plans 16

d. Secure production capacity 16

e. Equitable access for under-served populations 16

f. Climate smart health products 17

g. Data sharing 17

h. Duration of commitments 17

i. Third party enforcements rights 18

j. Transparency 18

7. How will Unitaid apply these guidelines? 19

a. Designing access commitments 19

b. Provision of product funding support 20

c. Due diligence 20

d. Updates to these guidelines 21

1. Purpose of these guidelines on equitable access

These Guidelines are designed to help partners and applicants for Unitaid funding understand how Unitaid ensures that the health products it supports are widely adopted, available, affordable, accessible to people in LMICs, and how these approaches will be reflected in the funding arrangements established between Unitaid, its partners and the project implementers it selects.

Unitaid's mission focuses on tackling pressing global health challenges by finding innovative solutions to improve health outcomes for people in low-and middle-income countries (LMICs). It supports efforts to prevent, diagnose, and treat diseases such as HIV, tuberculosis, malaria, and their co-morbidities (e.g., hepatitis and cervical cancer, oxygen, pandemic preparedness), as well as issues in maternal, child, and adolescent health. Through its funding and partnerships to support the development, manufacturing, and supply of health products, Unitaid aims to accelerate equitable access to new and better health products for people in LMICs, saving lives and making global health responses faster, cheaper, more sustainable and more effective.

Effective engagement with the private sector is central to these efforts, with successful arrangements benefiting all parties. For example, by collaborating with pharmaceutical companies and diagnostic manufacturers, Unitaid helps develop and introduce innovative solutions. These engagements benefit patients by improving access to lifesaving health products, while providing opportunities for companies to create sustainable markets for their innovations. Unitaid holds that broad, equitable access is a shared goal, and that measures can be taken to ensure that the benefits from Unitaid's work reach the intended populations.

In addition, because Unitaid deploys public and donor resources to address public health challenges, Unitaid seeks to ensure that the resulting benefits are shared broadly and managed in the public interest, including through commitments to equitable access.

Private sector beneficiaries of Unitaid's investments will be asked to provide legal commitments designed to ensure their products meet the needs of LMICs and are made widely accessible and affordable. Access commitments will also be sought from the public sector or not-for-profit entities benefiting from Unitaid product funding support. The examples provided in these Guidelines are indicative because the commitments will be customized on a case-by-case basis to reflect the specific goals and arrangements for each initiative, together with the nature and extent of each parties' involvement. In all cases, commitments will reflect a reasonable, pragmatic, and proportional approach.

Ultimately, Unitaid's work ensures that health products supported by its funding are adapted, affordable and available, enabling them to be adopted by LMICs, so they can reach the people who need them most. These Guidelines serve as a roadmap for applicants and partners, fostering alignment with Unitaid's objectives, while promoting transparency and predictability in the funding process.

2. How are Unitaid's access requirements secured?

Unitaid will seek access commitments whenever it provides product support. The commitments will be reflected in legally binding contractual arrangements intended to secure equitable access to the products Unitaid is supporting.

If the Unitaid support is provided through a Unitaid project implementer, Unitaid's access requirements will first be established in the arrangements between Unitaid and the implementer. The implementer will then pass on Unitaid's access requirements in its contractual arrangements with private sector beneficiaries involved in the Unitaid-funded project. The implementer will be expected to secure legally binding commitments from the private sector entity to the access arrangements through appropriate contractual agreements. This ensures that Unitaid's access objectives are enforceable.

Commitments are typically developed following in-depth consultations with experts and stakeholders. It is important to ensure the commitments build on existing efforts and support the broader objectives of Unitaid and key partners. In this context, Unitaid engages closely with key LMIC stakeholders, including national and regional authorities and community and civil society representatives in LMICs, to ensure alignment with recognised LMIC public health priorities and planning. The willingness and ability for LMICs to ultimately adopt Unitaid's target health products, once equitable access conditions are achieved, will be essential to achieve scaled, sustainable access and impact. To facilitate this, Unitaid's funding arrangements may be designed to enable countries and public sector purchasers for LMICS to benefit directly from the access commitments Unitaid secures, with quality, price and volume commitments designed to be directly enforceable by LMIC ministries of health in some cases.

3. When does Unitaid seek access commitments?

Unitaid is likely to require commitments aimed at securing its access objectives if the product funding support falls within one or a combination of the following three broad categories:

a. Direct financial support

to developers, manufacturers or suppliers – e.g. paid as incentive payments, innovation rewards, funds for capital investment, funding of research and development (R&D) activities, concessional financing arrangements or advance purchase commitments;

b. Technical support

for the products in question. Technical support is provided to private sector entities commercializing the product but **does not usually involve direct payment of funds** to them. Within this category, technical support could include implementation of clinical trials or operational research to obtain regulatory approvals and/or provide a basis for WHO recommendations with respect to the product, generation or provision of market intelligence and/or data, performing trial regulatory inspections (such as mock GMP inspections), regulatory file preparation, or investment case and demand forecasting;

c. Supply side interventions

aimed at creating healthy, sustainable markets or stabilizing markets, or de-risking a manufacturer's participation in the market – e.g. through catalytic procurement contracts, co-payments or volume guarantees.

Unitaid may also consider whether to seek access commitments before funding demand generation activities, such as product awareness campaigns and healthcare provider training, recognizing that these types of activities also benefit product developers and their commercialization partners.

Where Unitaid funding is provided indirectly through a Unitaid project implementer, that implementer will enter the contractual arrangements with the private sector beneficiary of the product support. Unitaid's approach to designing access commitments will be designed to achieve the same outcomes, regardless of whether product support is provided directly by Unitaid to the private sector beneficiary, or indirectly through the Unitaid project implementer, as described in Section 2. Unitaid will also require access commitments to be passed on to public sector or not-for-profit private sector entities, where they are responsible for the development and/or commercialization of the supported product.

Where product support is provided indirectly through a project implementer, Unitaid may still choose to develop and maintain a direct channel of communication with the private sector beneficiary of the support and may participate in negotiations of the terms applicable to the support, including access commitments.

Unitaid will seek to ensure that other relevant and specified global health stakeholders (such as follow-on funders and scale-up partners a) are able to take advantage of access commitments negotiated by it and/or its project implementers including, for example, price and volume commitments for a particular health product.

4. What are Unitaid's access objectives?

Unitaid's access objectives and strategic priorities will vary depending on the profile of the supported product but as a minimum, in all cases, Unitaid considers that equitable access means that a product is:

- **Adapted to LMIC context:** the product must be designed and suitable for the needs, infrastructure, regulatory environment, and resource constraints of low- and middle-income countries, ensuring effective use and impact in these settings. Ease of use may also be considered;
- **Affordable:** the product must be available for purchase at an affordable price, at least to public sector purchasers aiming to supply the product in relevant L/MICs. Affordability in the private sector may also be relevant in certain circumstances as further set out in paragraph 5(C) below. Affordability of pricing will be assessed with reference to the considerations highlighted in Section 5 below;
- **Available:** the product must be available in appropriate formulations or formats, and it must be registered and/or have obtained a marketing authorization from the authorities in relevant LMICs;
- **Supplied in sufficient volumes and with overall supply security:** the product must be supplied in sufficient quantities in a timely manner in relevant LMICs, in order to prevent stock-outs. The supply base should be diversified to ensure supply security and promote competitive pricing, whenever levels of demand are sufficient to sustain multiple suppliers. There should be no intellectual property barriers preventing the development of a healthy market for the product; For medical devices and related equipment, adequate maintenance arrangements (e.g., service level agreements, reverse logistics) and the availability of spare parts or consumables must be ensured.
- **Quality assured:** the product must meet, or aim to meet, appropriate quality standards, such as WHO Prequalification status or approval from a Stringent Regulatory Authority or WHO Listed Authority;
- **In demand by relevant LMICs:** there should be sufficient demand for the product, such that relevant authorities in LMICs confirm their interest in adopting it and are willing to incorporate it into national policies, guidelines, and programmatic use. Moreover, equitable access should be sustainable over time. As countries progressively transition toward greater domestic financing of health products, Unitaid seeks to ensure that market-shaping gains achieved through its investments are maintained, enabling countries to continue benefiting from affordable prices, quality-assured products, reliable supply, and procurement mechanisms that support long-term access.

5. What will access commitments look like in practice?

Unitaid will require access commitments aimed at achieving, as a minimum, the equitable access objectives listed in Section 4 above, from the private sector beneficiaries of product support.

This Section outlines the types of commitments likely to be required by Unitaid to secure these objectives, together with some of the considerations driving Unitaid's requirements. Additional, more targeted commitments may also be required based on further product and market analysis, as explained in Section 6.

a. Affordability

Unitaid will require private sector beneficiaries to commit to making the supported product available at an affordable price, at a minimum, to public sector purchasers seeking to supply the product in relevant LMICs. Unitaid may also seek to include the private sector within the scope of certain access commitments where relevant and on a case-by-case basis. Pricing commitments will usually reflect one of the following approaches, although others may also be used as appropriate:

i. Benchmark or target price

Where relevant market data is available, Unitaid will consider setting a target or benchmark price. This may be possible, for instance, where appropriate comparator products or interventions exist, or when reliable information on production costs or on the willingness or ability to pay is available. Although Unitaid will never require a private sector beneficiary to sell a product at below its Cost of Goods Sold (COGS), measures aimed at sustainable cost optimization may be sought.

ii. 'Cost-plus' pricing

Cost-plus pricing will be based on an analysis of supply-side factors, to identify the lowest sustainable competitive price level for the product to be supported by Unitaid (at different volume thresholds if applicable). The price will usually cover the cost of raw materials and production costs, plus a reasonable but modest margin, including a return on investment for commercial investors where relevant, to help ensure the economic sustainability of the production and distribution**. Where Unitaid will be supporting products that are already in production**, Unitaid will require optimization of cost structures and margins, to ensure the product is available at the best possible sustainable price. If it is considered that COGS could be optimized further, commitments may be sought requiring that manufacturers take steps to introduce efficiencies and increase their productivity, immediately or over an agreed timeframe.

iii. Tiered pricing – different prices may, where justified, be applied for different countries or geographical segments based on income level, volumes, ability to pay and other factors to improve access and affordability.

In addition to assessing the supply-side factors described above, **there will also be a need for pricing commitments to reflect the affordability expectations of the target purchasers, including key procurers, and the optimal level of pricing required to trigger their demand.** The ability of key procurers for LMICs to pay often determines overall volumes of demand and therefore whether products are scalable. Higher volumes may also result in lower unit costs. Price set based on the supply-side factors described above (including, for example, COGS) will sometimes still be higher than the affordable price. In these cases, Unitaid will consider strategies to address the price mismatch, including COGS optimization and implementing supply side interventions. Unitaid will design its access commitments accordingly including, for example, consideration of volume-based pricing commitments including volume triggers that automatically bring about further price reductions when agreed thresholds are met.

Where Unitaid provides funding for product development activities and the products are not yet produced at scale, Unitaid may seek commitments intended to ensure future production efficiencies and climate-smart, low environmental-impact production - e.g. commitments to develop the product in a way that minimizes its future costs of production and carbon emissions; and setting up a manufacturing and supply chain model that minimizes the cost of goods and climate impact.

Where essential key information, such as manufacturing costs and market size, is unavailable at the time of the conclusion of the funding agreement, the parties may be unable to determine and set an affordable price. The access commitments may therefore include provisions setting out an agreed approach and timeframe, to allow the price to be set once the relevant information is available, as further described in Section 7.

Access commitments may also include **conditions that allow for verification or audit of costs and/or COGS, as well as verification of compliance with any pricing commitments following execution of the agreement. There may also be provisions allowing the re-assessment or adjustment of target prices or pricing approaches (including consideration of distributor margins where appropriate**. Where such conditions apply, Unitaid will require commitments from private sector beneficiaries to disclose their development and production costs, together with sales data such as revenues, prices (including the landed price, or price ultimately paid by the procurer or patient, taking into account any distributor margin), units sold and marketing costs (subject to confidentiality if required). This will be particularly important if the price of the product
is to be determined on a cost-plus basis.

b. Availability

Unitaid requires that private sector beneficiaries of product support commit to make the supported products available for purchase in the LMICs that comprise Unitaid's defined target geographic market for the product. This may involve commitments to seek registrations or market authorizations in countries within the target market, particularly where waivers are not available based on the product having been prequalified by WHO.

The target market will be defined on a case-by-case basis and will vary according to the disease, the type and characteristics of the supported product, and Unitaid's specific access objectives. Other relevant factors for consideration when determining conditions designed to secure availability may include the disease burden in absolute and relative terms, the levels of income of the countries and/or the target populations, the focus countries in which Unitaid proposes to fund the implementation of projects involving deployment of the products (if applicable), and the capacity of national health systems to absorb volumes of the product (including consideration of distribution and supply chain models).

Unitaid aims to ensure that all LMICs can ultimately benefit from the access conditions secured through its projects. In some cases, the agreed access conditions may initially only apply to a subset of specific target countries benefitting from supply side interventions. In these cases, Unitaid will continue working to secure the expansion of the access conditions to benefit other LMICs in later stages.

c. Supply security

Unitaid requires private sector beneficiaries to make commitments aimed at ensuring **adequate and timely supply of the product** supported by Unitaid to LMICs within the target geographic market. This may involve, for instance, securing assurances and/or commitments in relation to production capacity, minimum production volumes, minimum order quantity and/or maximum lead time for delivery. Unitaid will also usually require private sector beneficiaries to commit to prioritize delivery against firm orders from public sector purchasers. Unitaid may also require commitments to ensure timely or accelerated supply to certain LMICs in the event of a specific need, such as an epidemic or pandemic. Mechanisms for fair allocation of scarce supplies may also be required under certain circumstances. If the product will also be marketed in high income countries, Unitaid may require that the beneficiaries implement measures to protect volumes destined for purchase by the public sector in LMICs. Such commitments may take into account the level of actual funding available for future procurement of a supported product. Unitaid may also seek the extension of access commitments to purchases by the private sector where substantial numbers of patients are seeking care for the relevant health condition in the private sector. The requirement to ensure access commitments benefit the private sector will be considered on a case-by-case basis.

Special conditions may also be designed to address the risk that suppliers or manufacturers could decide to stop or reduce the **supply** of their products to LMICs. Unitaid may, for instance, require access commitments from manufacturers or suppliers before implementing supply side interventions expected to create or expand a product market, Unitaid is likely to seek commitments to supply the defined market at no more than a defined affordable price for a minimum period and following the end of this period, provide a minimum amount of advance notice to Unitaid of any intention to discontinue or significantly reduce supply. Commitments may include measures to mitigate the risks for patients of any sudden discontinuation of supply. Requirements with respect to supply security will be generally proportionate to the level of Unitaid's investment. The risks of significant or permanent discontinuation of supply may also be addressed through the grant of IP "step-in" rights in favour of Unitaid or one of its partners or a requirement to issue a voluntary license of the intellectual property in the product to an alternative manufacturer or the Medicines Patent Pool. Unitaid will also consider requiring the reimbursement of product support and/or penalties in such circumstances.

d. Quality

Unitaid requires that the beneficiaries of product support make **commitments with respect to quality** and other relevant internationally recognized standards, in line with the basic principles of the Unitaid Health Product Procurement and Quality Assurance Guidelines (available on the Unitaid website). For example, Unitaid may require that they make best efforts to obtain and maintain WHO prequalification for the supported product, or approval by a stringent regulatory authority or WHO listed authority. Such obligations may also contain specific target timelines to facilitate rapid availability in relevant LMICs.

e. Demand and adoption

Although this is considered a key condition for securing equitable access, it is usually not the subject of legally binding access commitments. Unitaid seeks to secure demand and adoption of a health product through activities funded in its projects.

6. Other considerations related to access

This section sets out additional commitments which Unitaid may also consider, based on a case-by-case assessment.

a. Management of intellectual property rights

If product support results in or contributes to the **creation of new intellectual property rights in connection with the products**, Unitaid will require that the holder of the rights manages them in a way that furthers and is consistent with Unitaid's access objectives for the products. This does not mean that Unitaid will seek to prohibit beneficiaries of funding support from protecting new intellectual property rights and it can be important to do so. However, the rights must be managed in a way that does not restrict equitable access to the health products concerned. Relevant barriers arising from intellectual property rights may include patents, know-how, restrictive licensing terms, exclusivity arrangements, data or regulatory barriers, and limited freedom to operate; these may be addressed through appropriate licensing, sublicensing, non-assert commitments and technology transfer. Unitaid will therefore require, for instance, that any patents must not be used to impede or limit further research. Unitaid may also require voluntary licensing of intellectual property and tech transfer to generic manufacturers (and may provide funding to support such activities) as a means to ensure supply security, particularly where there is a sole supplier of a product and/or it is subject to patent barriers. Where relevant, Unitaid may also encourage early engagement with licensing partners, including the Medicines Patent Pool, as one way to manage intellectual property concerns and facilitate equitable access.

b. Use of step-in rights

When Unitaid funds the development of new health products, the conditions attached to Unitaid's funding will be designed to safeguard its equitable access objectives for the product. Equitable access will be put at risk if the product developer becomes unable or unwilling to complete its work, for instance, due to insolvency, or the merger or acquisition of the company. Unitaid addresses this risk by seeking **step-in rights to the product's intellectual property** (also sometimes known as march-in rights). Intellectual property will be defined quite broadly in this context, to include of any relevant know-how or technology necessary to complete the product development.

The step-in rights will be operationalized though the inclusion in the funding terms of a **conditional perpetual, royalty-free, sub-licensable license** of the intellectual property rights, in favour of either Unitaid or a designated Unitaid partner (such as the Medicines Patent Pool or another product developer). The conditionality of the license means that it will only be effective if one of the trigger events set out in the license occurs. These events usually include (i) the insolvency of the entity carrying out the product development; or (ii) its merger, take-over or sale with the resulting entity unwilling to commit to complete the product development on the agreed basis; or (iii) the termination or breach by the product developer of key terms of the funding agreement (including access commitments).

In addition to using step-in rights to protect investments in product development, Unitaid may also consider attaching step-in rights to funding for **market introduction and early-stage product commercialization**, to secure equitable access outcomes.

c. Use of equitable access plans

Unitaid may also consider requiring beneficiaries of its support to prepare an equitable access plan for the relevant product, setting out, in broad terms, how the beneficiary intends to ensure equitable access to the product by people in need in LMICs. Such equitable access plan may be prepared as either an alternative or complement to more specific access commitments. The content of the plan will be determined by Unitaid (in consultation with the beneficiary) based on, among other things, the profile of the product and its stage of development.

d. Secure production capacity

In the event that Unitaid has provided support for specific production lines intended to ensure production of products destined for LMICs, Unitaid may require specific commitments from the beneficiary to ensure such production lines remain available for manufacturing of the supported product (or other products able to serve relevant LMICs needs under the same production platform/line).

e. Equitable access for under-served populations

Unitaid may require commitments designed to secure access to the products it supports specifically for the most vulnerable, under-served populations within LMICs. These could include, for instance, requirements to develop, produce or supply paediatric formulations of treatments and/or diagnostics, treatments and/or diagnostics adapted for the paediatric population (such as taste masked formulations), or to ensure usability and performance through testing with diverse populations, and/or testing with populations/conditions represented in countries with a high disease burden (e.g., pregnancy, coinfections).

f. Climate smart health products

Where relevant to the product and intervention, Unitaid may include commitments that promote the development, procurement, and scale-up of climate-smart health products and supply chains, in line with Unitaid's Climate & Health strategy and its Climate-Smart Product Framework (https://unitaid.org/uploads/Unitaid-Climate-and-Health-Strategy-2023-2027.pdf). This includes considerations to reduce climate-related vulnerabilities across manufacturing, distribution, and delivery systems, while maintaining affordability, quality, and access objectives, as well as supporting the development and scale-up of health products and care delivery models responding to climate-sensitive diseases and evolving health needs driven by climate change. These considerations may also include efforts to minimise lifecycle greenhouse gas emissions (for instance in support of global net zero objectives), such as encouraging climate-adapted product design (including reduced fossil energy use and cold-chain requirements where feasible), more sustainable manufacturing processes, and supply chain configurations that enhance resilience to climate-related disruptions. Where relevant, these considerations will be applied in a proportionate manner and integrated into existing access commitments, including cost, availability, supply security, and product development requirements, without compromising the primary objective of ensuring timely and equitable access to essential health products.

g. Data sharing

Unitaid project implementers and recipients of Unitaid funding are required to comply with WHO's policy on open access. Unitaid will therefore require timely dissemination and publication of the outputs of all Unitaid funded research in the interest of achieving the access objectives, subject to any over-riding equitable access and/or ethical considerations, such as the need to protect individual confidentiality. Where relevant, Unitaid may also require that private sector beneficiaries waive data exclusivity rights in order to facilitate regulatory approvals of generic health products in relevant LMICs.

h. Duration of commitments

Unitaid will determine the duration of the access commitments required with a view to achieving its access objectives. It will therefore often require that access commitments remain in full force beyond the duration of the funding agreement between Unitaid and continue even if the agreement is terminated.

i. Third party enforcements rights

Unitaid may require that third party enforcement rights with respect to the access commitments are included in its funding agreements. These provisions will allow relevant third parties, such as the countries making up the target market or other public-sector procurers, to also independently enforce the access commitments set out in the legal agreement with Unitaid, rather than depending on Unitaid to do so.

j. Transparency

In order to ensure that scale-up partners and procurers of supported health products are able to benefit from access commitments agreed in relation to such products, Unitaid may require that certain key access commitments are made publicly available (or a summary of such commitments). These may include, for example, price and/or volume commitments, and definitions of target countries and purchasers/ procurers which may benefit from these commitments.

7. How will Unitaid apply these guidelines?

a. Designing access commitments

To ensure sustainability of impact of product support, Unitaid's access commitments will be designed taking into account the following principles:

- **Pragmatic and proportional:** Unitaid is committed to ensuring that its funding terms are pragmatic, proportionate and reasonable. The commitments required will therefore be determined having particular regard to the amount of Unitaid's support (both in itself and as a proportion of the total cost associated with the development of the product or the size of the transaction) and the relative benefit or advantage of the proposed product support to the recipient or private sector beneficiary of Unitaid support.

- Unitaid will consider the total benefit accruing to the beneficiary of its support and will design an approach which also leverages and builds on any actual or potential resources made available by other stakeholders in the global health response to support the roll-out or scale-up of the product (including, for example, funding for potential future procurement from public sector procurers).

- **Product profile and available information:** The scope and nature of the commitments required will also depend on the profile of the supported product, its stage of development, the characteristics of demand for the supported product, the information that is available on these points, and the amount of product support to be provided. Unitaid will assess these factors in conjunction with its own specific access objectives for the supported product when designing the commitments.

- Often the information required to establish clear access commitments is unavailable at the time of the conclusion of the funding agreement. In this case, Unitaid may include general commitments to access, with stage gates allowing for periodic review and revision by Unitaid of the access commitments as relevant information becomes available. This approach enables Unitaid to introduce more precise access commitments into its funding agreements as the supported product moves closer towards commercialization and/or scale-up.

- **Dedicated expertise and resources:** Where appropriate, Unitaid may include dedicated grant resources and/or access expertise to analyse product, intellectual property, and market conditions; define, vet, verify, and monitor actionable access commitments; and support linkage to post-grant monitoring where commitments extend beyond project timelines. Implementers may be requested to incorporate appropriate transition of access commitments monitoring beyond the project timelines where possible and subject to available funding and/or resources for this purpose.

- **Encouraging and promoting competition:** Unitaid recognizes the importance of competition between products and between manufacturers and suppliers as the basis for a sustainable market. Unitaid considers that a healthy, sustainable market for a particular health product will include at least two or three suppliers for the health product, unless exceptionally, demand for the product is too small to support multiple suppliers. Supply side interventions implemented by Unitaid will aim to create or encourage the development of such healthy competitive markets. Unitaid may also provide support for local or regional production of certain health products in order to promote equitable access and supply chain resilience.

- **Sustainability:** Unitaid recognizes the need for reasonable returns on investment for product developers, manufacturers and suppliers, in order to ensure continuity of production and supply, and to contribute to the creation of a viable and sustainable market.

b. Provision of product funding support

Payment for performance: Where private sector entities receive Unitaid's support in the form of financial payments, or incentives, payment will usually be made subject meeting pre-defined milestones, which may include the achievement of access commitments.

c. Due diligence

Unitaid conducts due diligence before entering into funding agreements, with a view to ensuring that its target products can be made available in line with the access objectives and that the beneficiary of Unitaid's support is, or will, be able to provide the commitments Unitaid requires.

The due diligence will include reviewing relevant **commercial and market information**, such as the commercialization plans of developers, manufacturers and suppliers Unitaid may seek the disclosure of development and production costs, together with actual and projected production capacity and actual or projected sales data, such as revenues, prices, units sold and marketing costs.

Unitaid may also request information regarding the ownership of the **intellectual property** for the target product. This will include relevant **patents or patent applications**, together with any in and out-licenses pertaining to the target product. Unitaid will also seek full disclosure of any rights granted or commitments made to third parties in relation to the product, such as exclusive rights to manufacture or distribute. In this context, relevant third parties could therefore include, for instance, (i) owners of intellectual property in components of the product which Unitaid proposes to support; (ii) other financing agencies, donors or investors, who may have secured rights or obtained commitments (including access commitments) as a condition for earlier upstream funding support or ongoing investments; or (iii) the potential manufacturers and distributors of the supported product.

In each case, Unitaid will require information and/or evidence that any patents, licenses, or pre-existing rights or commitments will not prevent either the achievement of Unitaid's access objectives or the making of, or compliance with, access commitments by the recipient of Unitaid funding support and/or the beneficiary. In addition, Unitaid will also usually require similar information concerning additional know-how, such as operating procedures, which would be necessary to exploit a license to produce the product, if a license is ultimately triggered, as described in Section 7.B above.

Insofar as the information exists, information requested as part of the due diligence process must be provided to Unitaid before a funding agreement can be concluded. Where the requested information, including details of the rights held by third parties, is subject to confidentiality commitments in favour of a third party, Unitaid will expect the applicant to actively pursue and secure a waiver of the confidentiality requirements from that third party, in favour of Unitaid, without delay.

Unitaid will usually require **contractual warranties** in its funding agreements regarding the accuracy and completeness of the information provided to it during the due diligence process. In some cases, warranties may also be sought as an alternative to conducting detailed due diligence.

d. Updates to these guidelines

Unitaid may make updates to these guidelines as and when deemed necessary. Any updates will be made publicly available on Unitaid's website.

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About Unitaid:

We save lives by making critical health products available and affordable for people in low- and middle-income countries. We work with partners to identify innovative treatments, tests and tools, help tackle the market barriers that are holding them back, and get them to the people who need them most – fast. Since we were created in 2006, we have unlocked access to more than 150 groundbreaking health products to help address the world's biggest health challenges, including HIV, TB and malaria; women's and children's health; and global health emergencies. Every year, about 390 million people benefit from the products we've helped roll out.