



Response by Médecins Sans Frontières to the invitation to comment on CEPI's Policy Regarding Equitable Access

Note: We are happy for our comments to be posted publicly.

It is MSF understanding that CEPI is revising its policy regarding Equitable Access in order to address a perceived concern from vaccine pharmaceutical corporations that the existing policy is 'too proscriptive regarding how it would be implemented', and as such 'inhibited CEPI from fully achieving its mission'¹. In approving the existing policy on 20th February 2017, the Board asked for a review after one year 'for initial assessment of alignment between policy and its implementation and interpretation.'² The purpose of the review as requested by the Board then was to review alignment and interpretation rather than to adjust the policy based on the perceived concerns of 'some stakeholders' that the policy is too proscriptive.

Although it is certainly useful to CEPI to assess and adapt its policy taking into account practical feedback, revising the Equitable Access policy before it is even implemented is premature. CEPI should in line with its transparency policy make the summaries of agreements signed till date available, along with the existing and the proposed draft of the new Equitable Access policy, so that an open and informed analysis can be done based on actual experience and benefiting from inputs from third parties, to contribute to the revision of its Access policy.

Having commented on the existing policy when it was developed, we would like to react to the revisions that have been made. Our feedback is guided by our experience as a medical treatment provider that is often one of the first responders to emergencies and outbreaks. It is also based on our experience of working for over fifteen years on access and innovation through the MSF Access Campaign, including in the area of vaccines, and through DNDi which MSF co-founded..

1. The critical importance of transparency

MSF welcomes CEPI's approach to transparency as set out in both the existing Equitable Access Policy and their Transparency and Confidentiality Policy.

CEPI's Transparency and Confidentiality Policy³ states under paragraph 1.2 that, 'the effectiveness of CEPI's programmes will be strengthened by public access to information, and that broad availability to the public of information about CEPI's activities will increase understanding and support of CEPI's mission.'

¹ P.1, CEPI, 'Invitation to comment on CEPI's Policy Regarding Equitable Access', http://cepi.net/sites/default/files/Access%20Policy--Public%20FINAL_1.pdf

² P.13, CEPI, 'CEPI Policy Documentation', approved by the Board 20th February 2017, <http://cepi.net/sites/default/files/Policy%20Documentation%20-%20v2.0%20-Sept2017.pdf>

³ CEPI, 'Transparency and Confidentiality Policy' available at <http://cepi.net/sites/default/files/Transparency%20and%20Confidentiality%20-%20v1.0%20-%20Aug2016.pdf>



In the draft revised Equitable Access policy for consultation⁴, CEPI states that it ‘is committed to prioritizing transparency in its own actions as well as encouraging other stakeholders, including CEPI partners, to share information and materials in a *wide-spread and timely manner* while respecting and protecting patient privacy and safety and partner IP.’ The document further states that, ‘It is CEPI’s conviction that a policy of transparency that provides for the availability of data relating to the testing of CEPI-funded vaccines while respecting and protecting patient privacy and safety *is of importance to stimulate wider innovation.*’ (emphasis added).

Building on these important broad statements of principle, CEPI has specified how this commitment to transparency will be implemented in practice. CEPI’s existing Equitable Access policy⁵ states that, ‘a summary of the provisions in agreements which CEPI enters into with awardees will be made publicly available unless there is an exceptional reason not to, which *would require Board approval.* It is anticipated that the summary will focus on equitable access obligations, shared risks/shared benefits arrangements and management of IP.’ (emphasis added).

Further, section 3 on ‘disclosure categories’ of CEPI’s Transparency and Confidentiality Policy sets out what documents will be made publicly available, through posting on CEPI’s Website. It includes:

- A summary of each Board meeting following their approval by the Board, including the decisions approved by the Board and accompanying Board reports.
- A summary of each Scientific Advisory Committee (“SAC”) meeting following their approval by the SAC, including the full text of decisions approved by the Committee and accompanying SAC reports.
- A summary of each of the other CEPI Committees meetings following their approval by the applicable Committee and after the next Board meeting, including the full text of decisions approved by that Committee.

2. Concerning trend: CEPI renegeing on its commitments to openness and transparency

We note with concern that CEPI is currently not in line with its own policy on transparency and confidentiality⁶. At the time of writing, the latest Board Meeting summary notes on CEPI’s website date from 21st September 2017⁷, almost a year out of date. The only summary note from CEPI’s SAC meetings that is available on the governance page of CEPI’s website is from October 2016. No other committee meeting summaries are available in this section (nor available elsewhere on the website in an obviously accessible or logical location).

⁴ P.5, CEPI, ‘Invitation to comment on CEPI’s Policy Regarding Equitable Access’, http://cepi.net/sites/default/files/Access%20Policy--Public%20FINAL_1.pdf

⁵ P.8, CEPI, ‘CEPI Policy Documentation’, approved by the Board 20th February 2017, <http://cepi.net/sites/default/files/Policy%20Documentation%20-%20v2.0%20-Sept2017.pdf>

⁶ CEPI, ‘Transparency and Confidentiality Policy’, approved by CEPI Interim CEO 24th August 2016, <http://cepi.net/sites/default/files/Transparency%20and%20Confidentiality%20-%20v1.0%20-%20Aug2016.pdf>

⁷ CEPI, ‘CEPI Governance’, <http://cepi.net/governance>



Moreover, CEPI is not complying with its existing Equitable Access policy as it relates to the transparency of signed agreements. We understand that 5 agreements between CEPI and awardees have been signed to date, and another 7 are expected to be finalised in the next month (JCG meeting minutes May 2018). The first of these, between Themis Biosciences and CEPI was announced in a press release on CEPI's website on 7th March 2018⁸. So far, no summaries of the provisions in agreements which CEPI has entered into with awardees have been made publicly available. This is in breach of both the current and revised draft policy on Equitable Access. In the process of revising their Equitable Access policy, CEPI proposes to take away Board oversight of any decision not to publish the provisions of agreements entered into with awardees. The revised text reads as follows, 'a summary of the key provisions in agreements which CEPI enters into with awardees will be made available unless there is an exceptional and compelling reason not to do so. It is anticipated that the summary will focus on equitable access obligations, shared risks/shared benefits arrangements and management of IP.'⁹

Recommendations

- 2.1. MSF urges CEPI to **implement its existing commitments to transparency without further delay**. In particular CEPI must publish:
 - 2.1.1. the summaries of agreements entered into with awardees focusing on the elements relating to equitable access obligations, shared risks/shared benefits arrangements and management of IP.
 - 2.1.2. the summaries of Board meetings, committee meetings and SAC meetings in a clear and logical place on its website (e.g. under the section on 'Governance').
- 2.2. MSF request CEPI **not to water down their commitments to transparency**. In particular the revised policy must retain the requirement of seeking Board approval before any decision is taken not to publish a particular summary of an agreement entered into between CEPI and an awardee.

3. Data Sharing

CEPI's existing Equitable Access policy includes clear commitments to data and trial results sharing that should be retained and implemented without delay. It commits CEPI to ensuring that 'all data and information from CEPI-funded projects should be rapidly shared with affected countries (researchers, government officials, and the public) in ways they can understand and, as needed, act on the information.'¹⁰ It also commits CEPI to 'make use of global platforms for sharing clinical trial data and results in order to facilitate collaboration between stakeholders, and expedite regulatory approval and equitable access during a public health emergency.'¹¹

⁸ CEPI, 'CEPI Partners with Themis Bioscience to Advance Vaccines Against Lassa Fever and MERS', <http://cepi.net/cepi-partners-themis-bioscience>

⁹ P.6, CEPI, 'Invitation to comment on CEPI's Policy Regarding Equitable Access', http://cepi.net/sites/default/files/Access%20Policy--Public%20FINAL_1.pdf

¹⁰ P.6, CEPI, 'CEPI Policy Documentation', approved by the Board 20th February 2017, <http://cepi.net/sites/default/files/Policy%20Documentation%20-%20v2.0%20-Sept2017.pdf>

¹¹ P.6, CEPI, 'CEPI Policy Documentation', approved by the Board 20th February 2017, <http://cepi.net/sites/default/files/Policy%20Documentation%20-%20v2.0%20-Sept2017.pdf>



The existing policy¹² further sets clear requirements on data sharing for awardees, including:

- registering trials in a publicly accessible database before patient recruitment (for those conducting trials);
- sharing of data and results, including negative results, via an easily discoverable, public route (website or system) that includes a metadata description, where patient privacy is upheld, and the system follows a request-for-information-approach where requests are fulfilled subject to an independent review and approval step;
- sharing clinical trial results as close to real-time as possible and within 12 months of study completion in line with the WHO Statement on Public Disclosure of Clinical Trial Results (14 April 2015), and that awardees commit to a specified expedited timeline before trials commence. If a compelling rationale to postpone the release of data and/or trial results exists, exemptions can be made with CEPI's consent;
- publications produced with CEPI funding to be published by awardees on an open access basis, defined as immediate and unrestricted access free of charge, with maximum opportunities for re-use, and including the underlying data.

In the process of revising their Equitable Access policy, CEPI proposes to drop these clear commitments¹³ and instead sets out a range of approaches to transparency as 'examples' of what *could* be included in the agreements they conclude with awardees. In the absence of specific and concrete commitments to transparency, there is no guaranty of CEPI's ability to expedite regulatory approval and equitable access during public health emergencies.

Recommendations

- 3.1. MSF urges CEPI to **uphold its existing policy on data sharing** and to reintroduce its original own commitments on sharing and the requirements on awardees to register trials, share data and results, **including negative results**, in accordance with the **WHO Statement on Public Disclosure of Clinical Trial Results** (14 April 2015), following a specified expedited timeline set before trials commence, and publish on an **immediate and unrestricted access free of charge open access** basis.

4. IP Management, Affordability, risk and benefit sharing and ensuring follow-through of vaccine development

CEPI's existing Equitable Access policy sets out clear parameters for the contractual obligations between CEPI and awardees in relation to IP management, ensuring affordability, ensuring follow-through of vaccine development and risk and benefit sharing. We maintain that these obligations should have been more ambitious and further-reaching (see attached the initial feedback sent by MSF to CEPI on its original Equitable Access policy in 2017). However, we note with deep concern that these obligations are

¹² P.6, CEPI, 'CEPI Policy Documentation', approved by the Board 20th February 2017, <http://cepi.net/sites/default/files/Policy%20Documentation%20-%20v2.0%20-Sept2017.pdf>

¹³ P.5, CEPI, 'Invitation to comment on CEPI's Policy Regarding Equitable Access', http://cepi.net/sites/default/files/Access%20Policy--Public%20FINAL_1.pdf



now completely missing from the revised draft, and replaced by examples of approaches, without clear guidelines.

The revised draft retains a statement of principle, that ‘CEPI understands that the use of public funds to achieve its goals carries with it responsibilities for delivering vaccines for public health needs at a cost that ensures that CEPI-developed vaccines can be used as necessary to prevent or end an epidemic, and for supporting sustainable systems for manufacture and distribution.’¹⁴ Yet, without any ‘red lines’ in the policy, it is difficult to see how this principle will be upheld. Moreover, the existing policy¹⁵ set clearer standards for affordability that should be retained. It committed to a policy whereby prices would be set ‘as low as possible and as close to optimal marginal cost as possible’ while ensuring the price is ‘sustainable for the awardee to maintain manufacturing, supply, and availability.’

The existing Equitable Access policy¹⁶ also set out a process that would be followed in agreeing pricing obligations post-licensure that was both transparent and ensured that the investment of public money would be recognized and built into pricing decisions such that the public could be confident that they would get a fair return on the public investment made. That is to say the policy stated,

‘CEPI and the awardee will agree that obligations around pricing will be established through a transparent and agreed methodology that will relate to information about public and philanthropic investments/risks in the vaccine (made through CEPI or through other government- or foundation-financed incentives for developing vaccines lacking market potential), cost of goods, expected volume/scale of production, price of existing comparable products, cost of maintaining manufacturing capacity, procurement agreements (entered into by CEPI partners), and other mechanisms for recovering cost of manufacturing the vaccine, and other relevant information.’

The existing policy¹⁷ further specified that contracts signed between CEPI and awardees would include obligations on awardees ‘in terms of registration and launch of the licensed vaccine in countries, manufacturing and availability, volume of doses and regulatory steps to best facilitate timely and sustainable access for populations in need.’ As well as provisions to ensure that ‘in the event that ownership of the foreground IP changes hands, the obligations on the awardee under the individual contract will be novated –such that the obligations shall remain with the technology.’ However, the revised draft simply states that there will be a requirement to reach a ‘clear agreement with awardees regarding how relevant IP (both background and foreground IP) will be managed to fulfil the equitable access obligations, including when one company is bought by another.’¹⁸

¹⁴ P.3, CEPI, ‘Invitation to comment on CEPI’s Policy Regarding Equitable Access’, http://cepi.net/sites/default/files/Access%20Policy--Public%20FINAL_1.pdf

¹⁵ P.5, CEPI, ‘CEPI Policy Documentation’, approved by the Board 20th February 2017, <http://cepi.net/sites/default/files/Policy%20Documentation%20-%20v2.0%20-Sept2017.pdf>

¹⁶ P.5, CEPI, ‘CEPI Policy Documentation’, approved by the Board 20th February 2017, <http://cepi.net/sites/default/files/Policy%20Documentation%20-%20v2.0%20-Sept2017.pdf>

¹⁷ P.4, CEPI, ‘CEPI Policy Documentation’, approved by the Board 20th February 2017, <http://cepi.net/sites/default/files/Policy%20Documentation%20-%20v2.0%20-Sept2017.pdf>

¹⁸ P.4 CEPI, ‘Invitation to comment on CEPI’s Policy Regarding Equitable Access’, http://cepi.net/sites/default/files/Access%20Policy--Public%20FINAL_1.pdf



Recommendations

- 4.1. In order to protect the interests of populations in need of these vaccines and to build public trust and support for CEPI's sizable public resource investment, MSF urges CEPI to:
 - 4.1.1. **At a minimum retain the provisions set out in the existing Equitable Access policy as they relate to equitable access during an epidemic or a public health emergency of international concern; equitable access to the final product (post-licensure); transparent price setting; management of IP including follow through and step-in rights.** This includes:
 - 4.1.1.1. obligations on awardees in terms of registration and launch of the licensed vaccine in countries, manufacturing and availability, volume of doses and regulatory steps to best facilitate timely and sustainable access for populations in need;
 - 4.1.1.2. ensuring that in the event that ownership of the foreground IP changes hands, the obligations on the awardee under the individual contract will be novated –such that the obligations shall remain with the technology.
 - 4.1.1.3. a policy whereby prices for vaccines post-licensure would be set ‘as low as possible and as close to optimal marginal cost as possible’ while ensuring the price is ‘sustainable for the awardee to maintain manufacturing, supply, and availability.’
 - 4.1.1.4. An agreement that CEPI and the awardee will agree that obligations around pricing will be established through a transparent and agreed methodology that will relate to information about public and philanthropic investments/risks in the vaccine (made through CEPI or through other government- or foundation-financed incentives for developing vaccines lacking market potential), cost of goods, expected volume/scale of production, price of existing comparable products, cost of maintaining manufacturing capacity, procurement agreements (entered into by CEPI partners), and other mechanisms for recovering cost of manufacturing the vaccine, and other relevant information.
 - 4.1.2. **Improve upon the existing policy** to ensure that CEPI rather than the awardee owns all foreground IP generated with CEPI funding, and a non-exclusive licence is granted to the awardee that allows for non-exclusive, worldwide use without royalty, but for which the licensee cannot obtain royalties for subsequent uses. The policy should set out that any exploitation of that IP for other purposes must be tied to access conditions that meet or exceed those access conditions established under CEPI, irrespective of the purpose of the new product.
 - 4.1.3. **Improve upon the existing policy** regarding the treatment of background IP. CEPI should seek licenses to background IP, to the extent possible. Improve upon the existing policy to ensure that CEPI will negotiate terms with partners to ensure that they will not use any acquired and/or held IP in a manner that impedes equitable and affordable access to the products of the research, or that impedes additional or follow-on research by CEPI, its partners and other researchers, especially those undertaking research on vaccines for priority infectious diseases.
 - 4.1.4. **Improve upon the existing policy** by including a clear statement that CEPI will not pursue additional, secondary patents that serve only to ever-green the relevant technology, and where possible, CEPI should consider a strategy of ‘publication’ of such IP to enable such IP to be available immediately in the public domain for widespread use.



5. Access to know-how : Lessons learned from rVSV vaccine platform

In vaccine development, access to know how is important. Knowledge and expertise including but not limited to purification techniques, cell lines, materials, software codes and their transfer of this to alternative manufacturers in the event the awardee discontinues development of a promising vaccine is critically important. The recent example of Merck abandoning the development of rVSV vaccines for Marburg (rVSV-MARV) and for Sudan-Ebola (rVSV-SUDV) is a case in point. Merck continues to retain vital know-how on the rVSV platform as it developed the rVSV vaccine for Zaire-Ebola (rVSV-ZEBOV) with funding support from GAVI. While it has transferred the rights on these vaccines back to Public Health Agency of Canada, there is no mechanism to share know how on the rVSV platform with other vaccine developers who would like to also use rVSV as a vector against other pathogens.

Recommendations

- 5.1. MSF urges CEPI to **retain the provision set out in the existing Equitable Access policy** which entitles it to activate arrangements agreed up-front in the contract, for accessing the awardee's know-how, and other undisclosed knowledge and materials related to the vaccine candidate in cases where facilitating technology transfer to one or multiple third-parties is deemed necessary to advance development of the vaccine candidate or achieve equitable access obligations.