CEPI (Coalition for Epidemic Preparedness Innovations): Inputs to OHCHR study on access

[CEPI](https://cepi.net/), an innovative global partnership working to accelerate the development of vaccines against epidemic and pandemic threats, is pleased to respond to the OHCHR [analytical study](https://www.ohchr.org/sites/default/files/documents/hrbodies/cescr/cfis/access-medicine/nv-call-input-access-medicines-vaccines-eng.pdf) on key challenges in ensuring access to medicines, vaccines, and other health products (HRC resolution 50/13).

Please see our responses below.

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1. **What are the major obstacles at the national, regional and international levels to ensure equitable access to medicines, vaccines and other health products?**

Inequitable access to health products remains one of the major challenges of global health and international cooperation. It is a vastly complex issue, and making progress requires concerted action across different sectors and geographies. Access may be considered on the basis of availability, affordability and accessibility.

* Availability refers to the product existing in the first place. The global R&D ecosystem can favour research into products which are profitable, often excluding medicines/vaccines for diseases prevalent in low-income countries or vulnerable populations (see below), products that are designed appropriately for low-resource settings, and products with an uncertain market (e.g., to tackle antimicrobial resistance (AMR) or viral threats with outbreak potential). In addition, most R&D and manufacturing capacity is concentrated in high-income regions, where prioritisation is focused on high-income country needs and testing is done on those populations only. There is also the lack of appropriate input into the global R&D agenda which often omits or delays the development appropriate health products suitable for poorer regions with less sophisticated health systems.
* Affordability refers to the ability to pay for a product. Disparity in ability to pay for a product can occur within and between countries. Countries with less purchasing power will be left at the back of the queue, particularly when supply is limited, such as in an outbreak situation.
* Accessibility refers to a product being licensed for use in a particular country, purchased by that country / their health system, and then delivered to those who need them. Various obstacles arise throughout this whole process, including difficulties in registering products in all countries, a country’s purchasing power, transport requirements (e.g. cold-chain), delivery system capacity and patient engagement.

It is also important to think about the difference between routine products, and products required during an emergency, both of which have various issues towards global access. For CEPI’s perspective on global access to vaccines during outbreaks, and vision for a future system that produces equity as a natural output, please see [here](https://cepi.net/news_cepi/re-engineering-for-equity-cepis-vision-for-achieving-equitable-access-to-countermeasures-for-epidemic-and-pandemic-threats/).

1. **Please elaborate on the specific barriers, if any, that women and girls, older persons, children, persons living in poverty, or other persons or groups in situations of vulnerability or marginalization face in accessing medicines, vaccines and other health products.**
* Many medicines and vaccines are not licensed for the whole population: for example, those who are children, pregnant, living with co-existing conditions (particularly immunosuppressive conditions, like HIV, in the context of vaccine development) are often excluded from trials and licensure. More funding and prioritisation are required to appropriately include vulnerable groups in safety trials, which includes engagement from patient groups and robust safety measures.
* As well as licensure issues, there can be cases where R&D is not carried out on the whole population that needs the product. This is true of populations in different geographies, and between males and females (even from the cellular level). This means that any genetic difference between populations may not be accounted for in the R&D data. It is promising to see a concerted effort to prevent these kinds of gaps in clinical trial data generation.
* At the delivery end, marginalised groups are more likely to have issues with access to healthcare systems, so even if a product is licensed for them, they may not be able to receive or afford it. Vaccine hesitancy and other issues may also impede access to vaccines.
* The COVID-19 pandemic brought many of these known issues to light, as we saw that the most vulnerable groups were the least likely to be able to access countermeasures. Systems must be built now to support these groups that can be leveraged during health emergencies, including infectious disease outbreaks.
1. **Are there any legal or regulatory challenges that impact the accessibility and affordability of medicines, vaccines and other health products?**
* Indemnity and Liability: Lack of capacity to indemnify innovative technologies against liability re adverse reactions, thereby impeding earlier access to innovation.
* Limited to no capacity within National Regulatory Agencies or Ministries of Health to independently receive, review, approve and monitor regulatory dossiers of all medicinal products, but especially generics and biosimilars, creating long delays for entry of affordable products.
* Import duties, tariffs, and taxes that increase end costs of medicines and vaccines.
* Limited regulatory harmonisation and reliance across national, regional and international jurisdictions, resulting in wasted resources and prolonged approval timelines.
* Issues related to substandard and falsified medicines that require investments in quality assurance and supply chain security.
* Pathogen- benefit- sharing issues and IP challenges (see separate IP question).

**(d) Please elaborate on the impact of research and development models for pharmaceuticals and other health technologies, including emerging digital technologies, on the access to medicines, vaccines and other health products?**

* Research and development (R&D) for pharmaceuticals is still concentrated in the Global North, which means that products are normally prioritised for Global North needs, populations and settings. An increased effort to significantly geographically expand R&D capacity will go a significant way to remedy this.
* R&D is typically carried out by the private sector, meaning market failures arise when there are externalities which increase the risk of investment. R&D, particularly at the later stages, is very expensive, so companies look for a clear indication of profit potential. Various factors impact this and cause a market failure, for example: a particularly novel technology which may have a lower probability of success; a product targeted at populations in countries with lower ability to pay (e.g., medicines for neglected diseases); products which, by design, should only be used as a last-resort so demand is lower (e.g., antibiotics for drug-resistant infections); products which have uncertain demand (e.g., vaccines for diseases which may cause outbreaks); products where clinical trials are particularly difficult to carry out (e.g., for rare or difficult-to-diagnose diseases).
* Various methods can be used to address these market failures, particularly public-private partnerships can come into play when there is a public health need for industry investment. Examples are CARB-X and the AMR Action Fund for antibiotic development, and CEPI, the Coalition for Epidemic Preparedness Innovations, for vaccines for diseases with epidemic and pandemic potential. These all provide ‘push-incentives’ by investing in R&D. There are also innovations to provide ‘pull-incentives’, which incentivise the development of products by a promise of purchase, for example GAVI which procures vaccines for low- and middle-income countries, or the recent UK ‘subscription’ model for antibiotics.
* The R&D stage is also a critical opportunity for funders, particularly public ones, to build terms into contracts for product development which require actions that will contribute towards global equitable access to resulting products or technologies. If more public funders did this, it would increase the number of products and technologies available globally, and level the playing field for funders, such as CEPI, who are already negotiating these terms.

**(e) From your perspective, what are the main challenges in terms of international cooperation, partnerships and collaboration to ensure access to medicines, vaccines and other health products?**

* Governments have a duty to protect their own populations. Unfortunately, there is often a misunderstanding that protecting a nation’s own population is a different goal than protecting the World. As COVID-19 clearly displayed, infectious disease outbreaks quickly cross borders, and that is only increasing in probability with increased urbanisation and other environmental factors, and climate change. New pathogens, or variants of existing pathogens can emerge anywhere and impact the entire globe, and we need to work towards a common understanding that nobody is safe from pandemics until everybody is safe. International cooperation is critical to our collective global health security. It’s clear that we need to design a global system for pandemic preparedness and response that will produce equity as a natural output during a crisis; we cannot solely rely on new mechanisms to be created during an emergency itself.
* The world is facing multiple crises, such as infectious disease, food security, climate change and conflict. International cooperation is vastly complex, as countries all come with their own priorities, needs and preferred solutions. Access to medicines needs to remain at the top of political agendas. This has come to light in the negotiations for a Pandemic Agreement, for example. The world needs to ensure that mechanisms for international cooperation are inclusive and diverse, and a small number of countries do not make decisions for the rest without their involvement. There are many fora for international discussion about access to medicines, such as regional bodies, the G7 and G20, the UN and multilateral organisations. Ensuring cohesion between these processes can be a challenge.
* Strengthening international partnerships could help improve access by supporting better R&D coordination centred around equity and strengthening regulatory and manufacturing capacity.

**(f) What impact, if any, does the existing intellectual property rights regime have on access to medicines, vaccines and other health products. How can global efforts better address intellectual property rights and technology transfer issues to enhance access to medicines, vaccines and other health products?**

* We need pragmatic solutions that enable both business sustainability and equitable access. Open access to IP alone will not result in global equitable access to all health products. Technology transfer needs to come with appropriate capacity and critically, know-how, which requires willing and trusting partners on both sides. One way that we can improve this process is to build in requirements and plans for technology transfer from early in the R&D process, through including terms in funding contracts.
* We also need to ensure that we continue to build sustainable and networked R&D and manufacturing capacity in all regions, with supportive surrounding systems such as workforce availability, regulatory capacity and physical infrastructure. These systems should have inbuilt plans and capacity to pivot and potential scale-up activity in the event of a health emergency. Communities should decide on their own R&D needs to effect solutions to their health problems.

**(g) What are the main challenges to ensure the quality, safety and efficacy of medicines and vaccines?**

* Experience from COVID-19 demonstrated significant regional inequalities in capacity and resources to generate much-needed local or context-specific vaccine safety data during both clinical trials and vaccine rollout.
* For licensed products, the main challenges include maintaining GMP, risk of falsified/counterfeit products, risk of temperature excursions in the supply chain, human error in delivery.
* In an emergency, we also need to think about the above under emergency or accelerated approvals, which requires an appropriate balance between earlier access and comprehensive data depending on the benefit-risk profile.
* Clinical trial, manufacturing standards and inspection capacity needs to be improved around the world – also see [here](https://www.who.int/our-work/science-division/research-for-health/implementation-of-the-resolution-on-clinical-trials) and our answer (d).
* There is limited Global pharmacovigilance systems to monitor the safety of medicines, and in some cases, human capital with appropriate training.

**(h) What obstacles do you see to ensuring the affordability of medicines, vaccines and other health products?**

* Products need to be both affordable and sold at a price that allows sustainable business models for manufacturers. One way to control pricing is to use a cost-of-goods plus capped percentage formula, which can be mandated in funding agreements for R&D. Another way to ensure affordability for countries with a lower ability to pay, is through tiered pricing mechanisms, whereby higher-income countries pay more, essentially subsidising for lower-income countries. However, there have been high-profile cases where high-income countries do not accept paying more than others.
* The cost of R&D in part drives the high cost of health products. Influencing and mitigating against R&D costs and other cost drivers (to achieve systemic equity) through non-for-profit/public financing and/or public-private partnerships as well as negotiating to remove barriers to technology will go a long way make health products affordable.

**(i) What concrete recommendations would you make to enhance access to medicines, vaccines and other health products?**

The drive to achieve overall system equity where the connections between the various key stakeholders work together in concerted manner should be at the forefront of all efforts to achieve equitable access. Tinkering with pieces of the chain will create bottlenecks unless the entire chain is supported and connected. Recommendations include:

* Requirements for equitable access should be built into funding agreements for R&D of technologies and products by public funders.
* Global sustainable and networked R&D and manufacturing capacity in all regions, with supportive surrounding systems such as workforce availability, regulatory capacity and physical infrastructure. These systems should have inbuilt plans and capacity to pivot and potential scale-up activity in the event of a health emergency.
* Public-private partnerships that address push- and pull-factors are critical mechanisms to address market failures in R&D for health products.
* Agenda-setting for R&D needs to become more globally led and inclusive, with priorities that are relevant for countries of all income levels.
* International cooperation, including on political and technical levels is key to build an equitable R&D and delivery system for health products.

**(j) Please add any other information or data you would like to share that have not been covered above?**

* As the OHCHR completes this study, it will be important to ensure collaboration with the significant number of other stakeholders, including the [WHO](https://www.who.int/our-work/access-to-medicines-and-health-products) and various international mechanisms and organisations, who are also working on these topics, including the work towards Universal Health Coverage. The study should also look to recent reports on these issues, such as the Independent Panel for Pandemic Preparedness and Response, or the G7 Pandemic Preparedness Partnership. This coordination is required to avoid duplication and ensure international collaboration.