



## **OFFICIAL RESPONSE FROM ACT-ACCELERATOR THERAPEUTICS** **PARTNERS TO THE IFPMA**

*This response was sent on 19 May 2022*

Dear Mr Cueni,

We note your [letter](#) dated 9 May 2022 and are in agreement that our continued collaboration will be vital in supporting countries to introduce lifesaving COVID-19 therapeutics.

As partners in the Therapeutics Pillar, we are all committed to ensuring that vulnerable people everywhere can benefit from rapid access to effective COVID-19 therapeutics. We recognize the continued engagement of pharmaceutical partners with the ACT-A Therapeutics Pillar and their work on enabling development and commercialization of needed products, as well as, via voluntary license processes, supporting development of generic products. These are some of the critical steps on the pathway to ensuring we maximize the impact of emerging therapeutics. We remain hopeful that the pipeline will continue to advance the search for the most suitable pharmaceutical solutions to this fast-evolving pandemic as we work to resolve current roadblocks and support countries' pandemic responses.

**ACT-A partners (WHO, Unitaid, Global Fund, UNICEF, Wellcome) are committed to our ongoing collaboration with industry – but more is needed to achieve equitable access for all.** We have engaged with originator companies that are developing and bringing to market various therapeutics, consistently calling for broad access principles that can enable a scaled-up response in countries in need.

We have discussed with the pharmaceutical partners the need to support affordable and transparent pricing policies. Early visibility on pricing terms and availability of originator products can support countries to adequately plan and forecast, simplify procurement processes and increase the speed of the response.

We also seek sustained product access via support to expanded generic production and access in all low- and middle-income countries. We have seen progress in both these areas, but we need more to achieve our shared objectives.

In each of the areas of equitable geographic access, affordable pricing, pricing transparency, and expanded generic production, we have experienced impediments which have slowed down deployment of these new products. **We therefore continue to urge IFPMA and pharmaceutical companies to continue to collaborate with ACT-A partners on a pathway for equitable access for all low- and middle-income countries.**



An overall approach to product allocation was developed in late 2021, communicated to countries in February 2022, and to date has been launched for three different products, including a preliminary allocation for nirmatrelvir-ritonavir. Product allocation processes are only used when needed, including when supply is insufficient to meet demand. They are based upon the product's specific use case and, therefore, can only be issued following a WHO recommendation. A major operational challenge for countries to express clear demand for new products is transparency in geographic access and pricing information. A short description of the allocation approach is included in annex to this letter.

To ensure prompt and adequate uptake as products become ready for use, we are working to support country-level deployment. Building on the ongoing work to support early adoption with cross-pillar efforts (Unitaid/FIND country projects), ACT-A partners are mobilizing an additional US\$120 million, as announced at the second Global COVID-19 Summit on May 12, for procurement and country-uptake of oral antivirals and diagnostics to prevent hospitalizations and deaths from COVID-19 for those at highest risk. Together with USAID, ACT-A partners will support more than 20 countries to support uptake of test-and-treat programs; efforts that can be reinforced if additional funding is made available.

Finally, we should recognize that countries and ACT-A partners are facing significant budget constraints and uncertainty which impedes deployment of these new products, in addition to the waning political attention to the pandemic and low diagnostic usage. Your support for ACT-A partners and work with manufacturers to expand equitable geographic access, affordable pricing, pricing transparency, and expanded generic production is appreciated and will support effective deployment of new therapeutics.

The ACT-A Therapeutics pillar's priority remains to **secure access, procure affordable products** recommended by WHO guidelines, **and support prompt and adequate deployment** of these life-saving tools. We look forward to continuing to work together to achieve these objectives.

Yours sincerely,

Mr Philippe Duneton  
**Executive Director, Unitaid**

Dr Mariângela Batista Galvão Simão  
**Assistant Director-General, World Health Organization**

Mr Peter Sands  
**Executive Director, The Global Fund**



## **Annex A: Overview of product allocation methodology and status**

Based on principles of equity, transparency, and ethics, as in the vaccine allocation strategy, and recognizing the different context of therapeutic medicines, an approach for equitable allocation was developed in late 2021 for COVID-19 therapeutic products. The development of the approach was accelerated and communicated to countries in February 2022 in anticipation of the release of tocilizumab. The allocation rounds were launched in mid-February and the supply agreement was signed on 15 March 2022.

Therapeutics allocation is initiated through an interactive portal that is accessible by country stakeholders. The portal is secured for multiple reasons including data privacy for countries; however, final allocation plans are shared transparently with countries, procurement partners and the relevant manufacturers. Respective manufacturers work closely with the ACT-A teams to optimize deliveries to countries, facilitate regulatory processes and other technical and operational activities.

The process captures complex variables, including adjusted needs estimates that identify appropriate target groups per the WHO treatment guidelines. It automates estimates to avoid long exercises at country level and also uses prioritization criteria to enhance supplies or timing to countries that are the most vulnerable. A typical allocation process takes 2-4 weeks to allow sufficient response times for countries.

In situations where constraints exist, they are also taken into account to ensure the best possible stewardship of therapeutics products such as avoiding over-supply. Constraints vary and can include supply, finance or country capacity to deliver necessary services e.g., ICU capacity for medicines used for hospitalized patients. Allocation exercises require a minimum amount of information and are best launched when there is sufficient visibility to the country on the terms, timing and quantities available.

Three different products have been launched via the Therapeutics Allocation Mechanism, including the innovator versions of Tocilizumab, Molnupiravir and Nirmatrelvir-Ritonavir.