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ACT-A THERAPEUTICS PILLAR AND ONGOING ROADBLOCKS TO ENHANCING ACCESS

Dear ACT-A partners,

As a founding partner of ACT-A, we remain committed to the collective goal of enabling global and equitable access to COVID-19 vaccines, therapeutics and diagnostics. Two and a half years on, the world is very much still in the grip of COVID-19 and we share the concern of our global health partners that we must redouble our efforts in order to defeat this pandemic.

The biopharmaceutical industry has stepped up to the challenge and done everything possible to meet what has been asked of us on facilitating access to therapeutics

Remarkable progress has been made in the fight against COVID-19 and this year particularly so on therapeutics. Antivirals can offer an important option for preventing severe illness, saving lives and preserving health system resources in the process. Our member companies have acted decisively early on by putting equitable access to antivirals at the top of our priorities. We have signed voluntary licence agreements (bilaterally and through Medicines Patent Pool) along with enabling the transfer of technology to scale up sublicensees' manufacturing capabilities. We have also engaged with ACT-A's procurement partners to put in place timely supply agreements for several million treatment courses to reach LMICs, while also submitting for emergency and full regulatory approvals and WHO pre-qualification in record time. In amongst all this, our companies continue to adhere to tiered pricing as a guiding principle for access.

Despite these efforts, we remain concerned that COVID-19 treatments are unlikely to reach those who need them in a timely and efficient manner due to a number of issues, many of which rest with ACT-A. We anticipated these and raised them on multiple occasions to the ACT-A partners, charting as far back as midway through 2021. However, many of these issues today remain unresolved and **if not dealt with promptly, run the risk of further exacerbating inequality of access to treatments.**

Cognizant that ACT-A alone cannot fully address such issues, we call on global partners to work collaboratively with us to help overcome three main challenges:

1. Demand signals, forecasts and purchase requests from ACT-A have been late and significantly lower than expected. This impacts access.

- We moved quickly to calls to deliver safe and effective antiviral therapeutics as soon as possible and at an affordable price. Yet, we have been surprised by the slow pace of concrete orders coming through the ACT-A Tx Pillar.
- Outside of the ACT-A pillar, certain LMICs have moved forward of their own accord to procure millions of courses of antiviral treatment in the past several months. This undermines equity between those LMICs with the financial ability to procure bilaterally and those which will rely on the ACT-A system to support procurement.
- Worryingly, demand in private markets supplied by generic manufacturers outside our members' voluntary licensing networks with unknown quality-assurance risks creating even greater inequality in LMICs where the public sector has not yet provided access.
- The procurement activities outside of ACT-A combined with the slow orders via ACT-A would suggest that roadblocks are occurring within the ACT-A system, and that countries have not been informed on how to access antivirals via ACT-A. These roadblocks are outside of our control and we urge that this be addressed as a priority.

2. An allocation framework for therapeutics should have been designed and coordinated with partners early on. This impacts access.

- Since June 2021, we have been calling for a clear allocation framework for therapeutics to be developed to provide guidance on how to ensure equity, knowing how important this would be for the manufacturers particularly when it was widely-known that volumes for some medicines would be limited in the early months of 2022.
- We are still no clearer about the timelines for the allocation framework anticipated by ACT-A. Such a lack of transparency and ongoing delays in allocation, lack of global funding and clear signals of supranational demand have made it difficult for manufacturers to forecast the supply needed to meet the ACT-A demand volumes.
- While manufacturers have set aside supply in the short-term to fulfil ACT-A procurement agreements that are now in place and they are now ready to ship product, the global health community to date has not provided a coordinated system for equitable access to antiviral treatments.
- ACT-A should streamline the procurement process with manufacturers through a single contract approach in support of access, thereby avoiding protracted negotiations with individual ACT-A partners. The current process is challenging given ACT-A partners place different procedural demands on manufacturers and operate different General Terms and Conditions, leading to cumbersome legal negotiations and unnecessary delays.

3. Country readiness risks slowing down treatment uptake. This impacts access.

- While innovator companies and their licensees continue to ramp up manufacturing to supply the world, we remain concerned that local systems will not have the absorption capacity for the new therapeutics to be most impactful in curbing the effect of the COVID-19 pandemic.
- Effective scale up of antivirals requires: availability of diagnostics; clear communication to patients on how, where, and when to seek testing and treatment, and information to

healthcare providers on the choice of which antiviral treatment option is most appropriate for which patient.

- We have consistently expressed our concerns about the preparedness of countries to absorb these new medicines into their pandemic responses. While we understand that work is underway in ACT-A to accelerate and enhance improved access to COVID-19 diagnostics and treatment while continuing to build capacity for test-trace-isolate and treatment efforts, we believe more must be done and reiterate our offer to collaborate on this important aspect.

In conclusion, whilst we continue to develop and supply the needed medical innovations to respond to the pandemic and to enable equitable access to the new therapeutics, we wish to share our concerns **that the ecosystem as it currently exists is not fit-for-purpose to ensure that patients have access to these treatments within the critical timeframes required, and not enough coordination seems to be in place to address identified access issues.**

I look forward to receiving your response to the issues outlined above, and remain as ever, committed to engaging with all necessary stakeholders in a pragmatic way forward to ensure we do what is best for those who need our treatments most.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'T. Cueni', with a stylized flourish at the end.

Thomas Cueni