



Dr Kewalramani,

We are a global coalition of CF patients, their families and supporters. Some of us are lucky enough to be seeing the amazing benefits to health from Vertex modulator drugs. Others are not and are desperate for access, literally dying waiting.

Vertex Save Us appeals to you personally as CEO, to address this situation by establishing a global access to CFTR modulator policy that would make the drugs available to everyone who needs them, wherever they live – with compassionate access prioritised. The UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines* specifies behaviours which Vertex is failing to abide by, resulting in fatal inequality.

We propose a 5-point plan to incorporate the recommendations within the Guidelines and save lives:

- 1. Provide free treatment to the sickest patients on the same basis, wherever they live, by year-end 2020.** An access scheme should be part of a published Human Rights Policy, so that compassion does not discriminate.
- 2. Make CFTR modulators available in all countries with CF** without delay, by ensuring that within 12 months all regulators have the latest data and health utility analysis for regulatory approval, noting your responsibility to “refrain from any conduct that will or may encourage a state to act in a way that is inconsistent with its obligations arising from national and international human rights law, including the right to the highest attainable standard of health.” (General, 7)
- 3. Price all CFTR modulators at affordable levels proportionate to each country’s situation** noting that “The arrangements should take into account a country’s stage of economic development, as well as the differential purchasing power of populations within a country.” (Pricing, discounting and donations, 34)
- 4. Establish “a publicly available policy on access to medicines”** (general, 13) – setting out global objectives, timelines, milestones and detail on how the policy will be operationalised by year-end 2020. **Assure top level, personal responsibility, for creation and delivery, and specify accountability for governance of the access to medicines policy** (Managing, monitoring, accountability 14); **ensuring the policy addresses how to overcome all barriers to access** including unaffordable co-pays, collaboration with health authorities to support testing and monitoring, and giving “particular attention to the needs of disadvantaged individuals, communities and populations, such as children, the elderly and those living in poverty.” (Disadvantaged individuals, communities and populations, 8)
- 5. In countries where Vertex does not have a short-term plan to supply its medicines, facilitate generic supply through open and transparent voluntary licensing agreements, not seeking or enforcing patents and other monopoly protections..and respecting countries’ right to pursue compulsory mechanisms to secure affordable, generic versions of all modulatory drugs;** respecting “the letter and spirit of the Doha Declaration on the TRIPS agreement and public health (2001) that recognises a state’s right to protect public health and promote access to medicines for all.” Noting the UN guideline to “issue non-exclusive voluntary licences with a view to increasing access, in low-income and middle-income countries, to all medicines.” (Patents and licensing, 30) **Allow all relevant trial and other data to be used to assist access to generics, include any necessary transfer of technology.** “As a minimum..(to) consent to national drug regulatory authorities using test data (i.e. the company should waive test data exclusivity) in least-developed countries and also when a compulsory licence is issued in a middle-income country.” (Patents and licensing, 30, 31)

We want to work with you to make global access a reality and invite you to give your response to the Plan, via virtual meeting with representatives from Vertex Save Us from around the globe. As this is a matter of extreme urgency, given that children and young people are dying right now, we ask that this be during the first two weeks of November. Please let us know your availability. The UN document is enclosed for your reference.

As you know, CF waits for no one and does not discriminate by geography, health system or wealth. We ask that Vertex CFTR modulators, which can transform the lives of CF sufferers, be available without discrimination also. We look forward, with hope, to your reply.

www.vertexsaveus.org

* Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines Published in the report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health (UN document: A/63/263, dated 11 August 2008).