

Brussels, 27 March 2020

Dear President von der Leyen,

Dear Commissioner Gabriel,

Dear Commissioner Kyriakides,

Europe is currently at the epicentre of a global pandemic of Coronavirus disease 2019 (COVID-19). At the time of writing, a rapid increase in the number of cases and deaths is still expected. In addition to ensuring the continuation of an effective public health intervention to contain the pandemic, there is an urgent need for a strategic medical response that is based on the evolving scientific knowledge of the disease. This must safeguard the development and availability of specially adapted and effective medical tools.

We welcome the European Commission's response to the crisis and the mobilisation of funds for research through the Horizon 2020 and IMI programmes. Programmes that aim to address, facilitate an improved understanding of the disease and the development of diagnostic tools, vaccines and treatments for COVID-19.ⁱ

Despite this we remain deeply concerned with how EU-funded medical tools and technologies for COVID-19 (diagnostics, vaccines and treatments) will be made available, accessible and affordable for patients in Europe and beyond. An effective pandemic response requires necessary medical tools to be affordable to healthcare systems and payers, and to be available free of charge at the point of care. We cannot allow patients to be refused care because of financial constraints or shortages resulting from manufacturing or supply constraints. From this moment forward, we require new medical tools to be immediately available once authorised for use, at an affordable price and in high enough quantities to meet global demand. This requirement aligns with the European Commission's ambition to ensure 'the supply of affordable medicines to meet its needs'.ⁱⁱ

We are appalled that some Member States have placed national interests over European solidarity, as shown by their efforts to ban the export of essential medical tools, and we are alarmed and shocked by reported efforts by the United States' Government to obtain an exclusive licence on a purportedly promising vaccine candidate developed by the German company CureVac.ⁱⁱⁱ If obtained, such a licence would allegedly provide the United States exclusive access to the vaccine. We stand firm that European Union efforts are, by contrast, guided by our founding values and principles of human dignity and solidarity, inside the Union and with the rest of the world^{iv}.

We note with great concern that while the European Commission invests more than double that of any private sector partners in EU-funded COVID-19 research projects^v, no legal provisions or requirements appear to have been put in place to ensure research outcomes will remain in the public domain and end-products will be made accessible, affordable and available for the patients and health care systems that require them.^{vi}

We must not allow private corporations developing medical tools with EU funding to place profit maximisation ahead of public health considerations at such a critical point in time. Granting monopoly and other exclusivity rights to private corporations could not only result in unjustifiably high-priced medicines and lengthy opaque price negotiations but would also lead to corporations likely being unable to meet global demands for any medicine developed. Exclusive monopolies would result in one or very few companies being allowed to produce an extremely timely medicine that is required in huge quantities worldwide. This will prove an impossible task and would put public health at risk in Europe and beyond.

In the absence of legal safeguards in grant agreements, the creation of private rights and the granting of exclusive licenses would constitute a handover of essential public-funded research outcomes to the private sector, potentially rendering essential scientific information secret, and life-saving products

inaccessible to millions. Applying such a ‘business as usual’ approach would be a waste of public resources and a grievous act of negligence on the part of EU institutions which have a responsibility to protect public health and stand in solidarity with their Member States and the rest of the world. This responsibility is even more critical in a time of crisis when societies look to EU institutions for guidance, support and leadership.

Non-exclusive licensing would enable the European Commission to grant multiple manufacturers a licence for production of the medical tool, allowing a rapid global upscale of production to meet demands in Europe and elsewhere. The resulting enhanced competition would lead to more affordable end-products. In addition, clear and enforceable requirements for fair and affordable pricing should be included in licensing agreements for technologies developed with public funds.

Given that the myriad of new therapeutics and diagnostics targeting the novel coronavirus are as yet unproven, expedient complete transparency of clinical trial data is crucial to inform evidence-based procurement and public health measures.

We urge the European Commission and IMI directorship to:

- Take necessary actions to ensure that patents and monopolies will not restrict production, and provide medical tools needed to combat the pandemic. Exclusive licences to any private manufacturer for a coronavirus diagnostic tool, vaccine or treatment in any grants, contracts, or licensing arrangements must not be provided. Other forms of worldwide non-exclusive licensing of resulting health technologies should be included as a precondition for receiving EU funding.
- Leverage its investment to demand transparency in the research and development (R&D) pipeline by providing full public oversight and accountability over public and private investment in the R&D of end-products, in order to guarantee that contractual access and affordability commitments and conditions are met.
- Take steps towards the creation of global governance mechanisms to ensure an allocation and supply of medical tools to assist in the control of the outbreak according to need . We cannot allow overstocking in one country or region of the world to lead to shortages elsewhere. This is particularly pertinent for low resource setting countries.

We are confident that the European Commission understands the urgent need to protect public health in the face of this unprecedented health crisis. We will continue to provide input where necessary to assist the Commission in ensuring essential diagnostics, therapies and vaccines remain accessible in Europe and beyond.

Yours sincerely,

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ⁱ https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/medical_en#research-and-innovation

ⁱⁱ *Mission letter from President-elect Ursula Von Der leyden to Health commissioner-designate Stella Kyriakides*, Brussels, 10 September 2019. https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf

ⁱⁱⁱ The Guardian, *Trump 'offers large sums' for exclusive access to coronavirus vaccine*. 15 March 2020 https://www.theguardian.com/us-news/2020/mar/15/trump-offers-large-sums-for-exclusive-access-to-coronavirus-vaccine?CMP=Share_iOSApp_Other

^{iv} Treaty of European Union, article 2. Official Journal C 326 , 26/10/2012 P. 0001 - 0390

^v The commission invests a total of €92,5 million from IMI and Horizon 2020 budgets for Covid-19 research compared to a pledged investment of € 45 million in in-kind contributions by the private sector. https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/medical_en#research-and-innovation

^{vi} The standard Horizon2020 eligibility criteria apply. HORIZON 2020 – WORK PROGRAMME 2018-2020 General Annexes https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-c-elig_en.pdf