2ND VIDEO CONFERENCE OF THE R&I DGS ON R&I ACTIONS ON COVID19: VACCINE DEVELOPMENT

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SUMMARY RECORD BY THE COMMISSION SERVICES

On 31 March, Jean-Eric Paquet, Director-General of DG Research and Innovation of the Commission, organised a second videoconference with the R&I DGs of the national administrations of the EU Member States to discuss the coordination of R&I actions on COVID19. This time the discussion focussed specifically on the fast tracking of vaccine development. Jean-Eric Paquet reminded Member States of the draft action plan circulated by DG R&I following the first videoconference. Member States are invited to comment on this plan in writing. The aim of this joint effort is to create a living framework, in which the EU responds to COVID-19 in a flexible way.

Jean-Eric Paquet referred to the documents circulated in advance of this discussion, especially on the global picture regarding vaccine development and the "Hackaton" to take place in the second half of April, which will be opened by Commissioner Gabriel. Jean-Eric Paquet also mentioned the Ministerial videoconference, which will be organised by the HR Presidency on 7 April (16:00 – 18:00 p.m.). HR confirmed the date and announced that the meeting should provide a platform for further exchange about R&I actions against COVID-19 in the short, medium and long term. The aforementioned R&I action plan will be a reference document for this meeting; HR considers to launch a Ministerial statement to endorse this plan.

Jean-Eric Paquet finished his introductory remarks by asking the Member States to communicate the joint efforts and to pass on to our citizens that, while the response to COVID-19 is centred around national health systems, it has is a very important European dimension. Everyone should highlight this when presenting progress of research projects, in particular on the DISCOVERY project on clinical trials, where in too many cases only the national component is mentioned. Following this, three representatives from the Commission elaborated on activities in the area of (funding) vaccine development:

Irene Norstedt (DG R&I) presented a slide with the simplified schematic description of vaccine development (see Annex I). Before going into details, she drew the attention of the participants of the VC to Research Infrastructures (RI), Transvac2, EATRIS and ECRIN, which can support the development done on the European level and which are supported by Member States' funding as well. Regarding vaccine development, this is a challenging and costly endeavour with the different stages of clinical trials to late stage trials to ensure the safety and efficacy of the vaccine. For the time being, developments are in the very early stages of this process with only a few vaccines moving into early stage clinical trials. In parallel to the clinical development, actions are needed to ensure the process development and prepare for the manufacturing of any successful vaccine. Today the manufacturing capacity is a major bottleneck for the large volume of vaccines that need to be produced. Therefore the manufacturing of vaccine(s) must be addressed in parallel with the clinical development. Currently, we are in the early stages of development, with a few exceptions of

early clinical trials of vaccines supported by CEPI. CEPI has developed a portfolio approach for vaccine development and manufacturing for global access for the successfully developed vaccines (2-3 vaccines). The European Commission and some MS contribute to CEPI, in addition investments by the European Commission and by Member States include funding for individual vaccine candidates. The question is how we can make best use of our investments to bring the development of these vaccine candidates forward. One question is therefore if a coordinated approach also for vaccine developments that are not part of the CEPI portfolio should be supported. In view of getting a better overview of the candidates funded outside CEPI, it would be good if the Member States could share which candidates they are funding, and which they consider as the most promising ones. It would also be relevant to know, in which stages of developments these are. Together, we should make sure that the best candidates receive support.

Andrzej Rys (DG SANTE) underlined the role of the European Medicines Agency (EMA). The EU regulatory system provides: mechanisms to speed up development and approval of medicinal products, including vaccines; scientific advice; EMA's PRIME scheme for enhanced scientific support to medicines for unmet needs; the accelerated assessment and conditional and 'under exceptional circumstances' marketing authorisation procedures. The EMA machinery is now focussed on this PRIME scheme and is helping in the development of potential new products. Developers, including SMEs and academia, can contact EMA directly and seek their fast-tracked scientific advice free of charge since two weeks. EMA is also working in a global network; on 18 March a workshop took place co-chaired by US and EMA with participants from regulatory institutions around the globe.The published report focuses on pre-clinical data requirements and the theoretical risk that vaccines against COVID-19 enhance the disease prior to starting first-in-human clinical trials. At the moment, we have no existing vaccine that would work against COVID-19. Mr Rys concluded that EMA has activated its plan for managing emerging health threats. An EMA Task Force (ETF) is convened as part of this plan. It includes the chairs of its main committees plus other relevant experts. The ETF mandate may include the following: provide advice to manufacturers on developing medicinal products, e.g. vaccines; contribute to product-related assessment; interact with stakeholders; and maintain European and International cooperation, including with WHO.

Jean-David Malo (DG R&I) pointed out that, in cooperation with the EIB, a wide range of instruments to support innovators under Horizon 2020 was developed to fight against infectious diseases. He mentioned explicitly the InnovFin Infectious Diseases Instrument (IDFF) under EIB. He also mentioned that the very visible support for the German company CureVac triggered many additional applications. InnovFin has already been reoriented towards support for research on COVID-19 and the EIC thinks about how to contribute in the best possible way, but the demand is increasing on a daily basis. Therefore, avenues to join forces with national funding e.g. in cooperation with promotional banks need to be explored. (More information in Annex II)

After these presentations, Member States exchanged views around three questions on national funding intentions on vaccine research and development, the necessity of fair and

ethical production and distribution of vaccines, as well as the pledge from Presidents Ursula von der Leyen and Charles Michel for coordinated vaccine research. While Member States reported about immediate calls and investments undertaken at national level, they also stressed the need for coordinated and joint efforts at EU level. An overview of current initiatives would be a helpful next step.

To make sure that Europe will have new and effective vaccines, Member States underlined that continuous investment in basic research is crucial. Member States trust that rapid developments can be reached via CEPI. ESIF funds should be made available in a flexible manner. However, the large-scale production of the (future) vaccine will need to be discussed with industrial partners. Member States repeated that data sharing is essential, especially to ensure the fair distribution of knowledge and production for future vaccines. IPR on COVID-19 research should be open and accessible to all Member States. In this context, many Member States welcomed again the efforts already done to establish respective platforms under EOSC and in cooperation with EMBL. Several Member States underlined the role of research infrastructures in general. Regarding the pledge by the Presidents of the Commission and the Council, Member States showed openness to participate, subject to more detailed information.

Referring to the follow-up of the videoconference on 24 March on general R&I actions on COVID-19, several Member States welcomed the draft R&I action plan as a good basis for a coherent EU roadmap to address COVID-19.

Jean-Eric Paquet concluded that there is need for strategic overview of how we can support vaccine development in the EU and globally, including data sharing and investments, such as via the EU and national contributions to CEPI. The Commission services will provide such an overview. Annex II of the discussion paper for this videoconference will be updated accordingly and might serve as the basis for a future pledging event, on which the Commission will come back to the Member States once more information will be available. Furthermore, a meeting with the national promotional banks will be organised in order to discuss and channel the needs of companies reaching out to the EIB. Regarding Horizon 2020, further adjustments are needed to the budget; the Commission will consult the Strategic Programme Committee configuration on possible amendments to the work programme as fast as possible.

Jean-Eric Paquet informed the Member States that the Commission will come back to them within the next few days. While as much as possible will be done in writing, he asked for flexible availability in these challenging times. The Commission will coordinate with the HR Presidency regarding the preparations of the Ministerial VC meeting on 7 April.

Based on the feedback from Member States, the three associated countries Norway, Switzerland and Iceland will be invited to participate in the next meeting on DG level. The Commission will share the outcomes of the discussions so far with them.