**3rd Video conference of the R&I DGs on R&I actions on COVID19**

**15 April 2020**

**Summary record by the Commission services**

On 15 April, Jean-Eric Paquet, Director-General of DG Research and Innovation of the Commission, hosted a third videoconference with the R&I DGs of the national administrations of the EU Member States to discuss the coordination of R&I actions on the Corona virus. Norway, Switzerland and Iceland also participated.

This time the discussion focussed specifically on: 1. The implementation of the ERAvsCorona Action Plan; and 2. The development and manufacturing of vaccines, treatments and diagnostics, linked also to the pledging event of 4 May. Jean-Eric Paquet stressed that time is of essence, also for the EU to show it can lead in this effort. Besides the EU countries, he also stressed the need to reach out to EU’s key partners, especially those who are associated to Horizon 2020, and to those with whom the EU has S&T agreements. He informed about a separate meeting to be organised with associated countries and the intention of sharing with these countries the relevant information. Feedback from that meeting will be presented at the next DGs meeting. He also informed that for Action 1 the proposal is to set-up an ad-hoc working group composed of the Commission, Member States and relevant agencies. The intention is to have a first meeting on Friday 17 April.

Before entering into the discussion about the agenda items, Jean-Eric Paquet invited **Jean-David Malo (DG R&I)** to provide an update on preparations for the upcoming **pan-European Hackathon**: Jean-David Malo informed the participants that institutions in all 27 Member States will participate in the Hackathon. In addition, organisations from six associated countries and from the UK are participating. Until now, there are already more than 100 organisations involved in the design of this initiative. In the meantime, the European Parliament and the Committee of the Regions gave their support to the initiative as well. As a next step, the Commission proposes to create a **group of representatives from the Ministries of the participating countries** to continue the dialogue with 4 main objectives: (1) Before the Hackathon takes place, this group should follow the progress of preparations and ensure a good balance of participation; (2) Still before the Hackathon takes place, measures addressing under-representation of Member States should be put in place immediately; (3) Furthermore, ambassadors (well recognised persons from the public or private sector, including Ministers, Prime Ministers or Heads of State) should be nominated in the countries to spread information about the event and to ensure adequate dissemination of information knowledge via the local (national / regional) media; and (4) after the Hackathon took place, the group of representatives from the participating countries should provide follow up to the best ideas developed in the Hackathon (this follow-up will be provided within the EIC Covid Platform where representatives of the Ministries will be able to find more details about the ideas developed by their nationals and provide adequate follow up). The Commission calls upon the participating states to set up this group immediately. **Nominations should be addressed as soon as possible to** Isidro.LASO@ec.europa.eu.

Following this intervention, Jean-Eric Paquet opened the discussion on the first agenda item, the **implementation of the first 10 priority actions of the ERAvsCorona action plan**, while acknowledging that some Member States already sent their comments in written form and encouraged **the others** to do as well. He asked participants to tackle Action nr. 1 during the second round.

Most Member States confirmed their support to the 10 Actions as well as the setting-up of the ad-hoc working group for Action 1. Several Member States asked for more information on the mandate of this working group. Member States highlighted that the Action Plan is a living document and referred to some specific actions and/or provided information on new national initiatives. Some stressed the importance of the international dimension and the need to look into the future, while keeping a balance between short and long term measures. In this context, reference was made to the high level Task Force which could ensure a scientific comprehensive approach and monitor the implementation of the Action Plan. A suggestion of using for that purposes an ad-hoc group of ERAC was made. The value of clinical trials was noticed while the importance of relying on existing structures was highlighted with a need to have the full picture of trial capacity. Questions were posted on how Member States could join ongoing clinical trials. Prioritization of vaccine development was stressed. A need for a more European approach in case of common methodology for sampling and testing was made. The importance of a discussion on a new call in the Programme Committee with specific reference to digital technologies was raised. To ensure a quick delivery it is needed to rely as much as possible on existing projects and impacts. The possibility to have a kind of “hop-on” to strengthen existing consortia with additional competence was suggested. Inclusiveness in projects and actions undertaken were raised. A call for a common approach to support to research infrastructures was made. Importance of citizens’ involvement was stressed.

All written comments provided by Member States can be found in the annex to this summary.

In his conclusion from the first item, Jean-Eric Paquet proposed that the agenda for the next R&I DGs videoconference could be drafted in close cooperation with the Croatian Presidency and Council Secretariat, in order to follow-up on the Ministerial videoconference of 7 April.

The second item on the agenda was a **discussion of the next steps on vaccine, treatment and diagnostics development and manufacturing**. Jean-Eric Paquet explained that the ad-hoc working group should: connect research and clinical trials, should consider how to streamline procedures with EMA, and to collectively look at how we can procure the outcomes in terms of tests and medicines.

Jean-Eric Paquet also referred to the **international pledging event**, which will take place on 4 May. This event is not only about funding, but also very operational, for example to identify certain vaccine candidates and to invest in production capacity. The event brings together EU Member States and third countries across the globe, involving the G7, G20, WHO, the Bill & Melinda Gates Foundation and the Wellcome Trust. While Member States will consider their national contributions, the EU should team-up for the event to showcase what we are able to do in Europe (which vaccines are trialled in the field; which are the timelines; which support is granted by EIB and promotional banks as well as industry).

**Maria-Cristina Russo (DG R&I)** underlined the importance of linking the efforts and inputs for the pledging event of 4 May with the EU’s key partners in Research & Innovation. She called for involving all countries with STI agreements as well as countries associated to Horizon 2020 as some of them, such as India or South Africa, have important positions from a geopolitical point of view. Cristina Russo informed the participants about a letter sent by the President of South Africa, on behalf of the African Union, to President Ursula von der Leyen. In this letter, he called for closer cooperation between the EU and African partners in the fight related to COVID-19.

Following this, two representatives from the Commission informed the Member States about the current state of play on vaccines, diagnostics and treatments:

**Irene Norstedt (DG R&I)** started by elaborating on the **tasks of the ad hoc working group** that should be established immediately in order to coordinate actions against the Corona virus. The aim of the ad hoc group would be to look at the complete vaccine, treatment and testing pipelines from research to deployment from a very pragmatic and operational aspect. The aim is to get an overview of joint efforts, to identify bottlenecks or challenges and to propose actions to ensure that ongoing developments can be progressed and deployed as quickly as possible. We see, for example, that as many new therapies are in development the need for access to clinical trials sites will likely become a bottleneck. It will be important that those most promising therapies in development rapidly get access and maybe given priority. How could this be done? Several questions arise, including:

1. How can we ensure that we best use the preparedness clinical trial networks and infrastructures in the best possible way and in a coordinated manner?
2. How can we assure that the most promising therapy trials rapidly get scientific advice to ensure that the trials are “regulatory fit”?
3. How can ethical approvals to start the trials be expedited rapidly without compromising the safety and application of sound ethical principles?
4. To develop a therapy is a costly endeavour. Funding for therapy development has been granted from Horizon 2020, will be from IMI2 and also from national funders, and from the EIB. How can we ensure that the most promising therapies do not fall into valleys of death due to lack of funding when the current grants are “consumed”?

These are typical issues to be looked at and whenever possible to identify ways forward to address such challenges. When it comes to vaccines**,** it is known that manufacturing will be a limiting factor. There are also different types of vaccines to be manufactured and different vaccination strategies to be developed depending on the type of vaccine. This will also put different demands on the number of doses to be manufactured and deployed.

The **aim of this ad hoc group is therefore to identify such questions for the three areas – therapies, vaccines and diagnostics**, and we should not reinvent the wheel. Existing groups of expertise should be used; this is particularly the case when it comes to areas under the responsibility of SANTE, for example the regulatory aspects.

The Commission therefore proposes that the **first meeting of this ad hoc group** would be to discuss and agree on the “pipelines and its challenges”, on the working methodology and to identify already existing “groups” who’s expertise can be drawn upon to address the identified challenges.

Regarding **vaccines**, Irene Norstedt stressed that it is important to collect the correct information from Member States contributing to CEPI and that it is ensured that we have a comprehensive strategy to address bottlenecks as quickly as possible.

Regarding **clinical trials**, the first priority is to join forces around setting up EU wide multi-centric clinical trials, such as the DisCoVery and REMAP-CAP trials, to investigate the efficacy and safety of COVID-19 therapeutic approaches including the use of convalescent plasma.

The WHO has launched the Solidarity trial, which is similar to the DisCoVery trial. It needs to be emphasised that: 1) the DisCoVery trial will (unlike the Solidarity trial) fully use the strong European research capacity and provide the necessary data also for regulatory purposes, and 2) both abovementioned trials build on the strong networks Europe has invested in over the past years. The Commission will work with these networks to ensure the necessary flexibility to include in the trials new therapeutic compounds as they become available from research, as well as candidate vaccines. The Commission would welcome further participation from Member States and therefore asks them to indicate which research sites are willing to join the implementation of one or both of these trials and whether the costs of the participation are covered or additional funding is sought.

Then the aim is to further develop an EU wide COVID-19 clinical trials network. As the work programme 2020 already dedicates EUR 30 million to the “Creation of a European wide sustainable network for harmonised large-scale clinical research studies for infectious diseases”, this could provide the platform to do so (these funds are already in the WP).

The ad hoc working group will further discuss how to bring effective COVID19 therapies to the patients by smoothening the path to regulatory approval and exploring the possibilities of joint procurement. Furthermore, the treatment accelerator is an international initiative launched by the Bill & Melinda Gates Foundation together with Wellcome Trust and Mastercard. The group will also discuss how synergies with this initiative could be created.

**Martin Seychell (DG SANTE)** underlined the necessity to address the **continuum between research, production and distribution**. This process would normally follow a linear development, which is not possible under the current circumstances. A major bottleneck in production capacity lies ahead of us, not only in Europe, but also in the global context. Martin Seychell pointed out that while in Europe we can focus on COVID-19, in other parts of the world the continuous production and delivery of other vaccines needs to be ensured as well. He informed about a Communication adopted by the Commission on 15 April on testing kits. Tests need to be reliable and effective to serve the de-escalation of the situation, which is also mentioned in the roadmap presented by Ursula von der Leyen and Charles Michel (also on 15 April). Coordination between the Commission and the Member States needs to be ensured in the use and form of tests and for selecting the right tools. Martin Seychell highlighted the importance of having a centralised overview of test performance in practice, which is where national inputs and strategies come in. He made reference to a network of laboratories for the exchange of information and the management of control samples. Furthermore, guidance is needed on conformity assessment and the comparison of devices. Unfortunately, as we see trafficking of counter-fit tools, this issue needs to be tracked as well. In the fight against the mismatch of supply and demand, a joint procurement mechanism could help to establish the fair distribution of stocks where they are most needed, based on realistic estimations. In a common effort, we should avoid shortages in resources and make sure that tests are possible where they are needed.

On clinical trials, Martin Seychell referred to the cooperation with EMA on standardised trials for robust and conclusive evidence based on critical mass, which is necessary for the approval of treatments. The DISCOVERY trial is designed to address regulatory processes, the by WHO developed trial SOLIDARITY can be used complementarily in order to create public health impact. A (third) revised version of guidelines for clinical trials will be published on 21 April.

In the following discussion, Member States stressed: that it is important to map clinical trials in Europe and that coordinated models are needed; that simple tests are needed based on common guidelines; that the global dimension of the pledging event should be taken into account (China, Russia and the USA were mentioned).

Jean-Eric Paquet thanked the participants for their inputs and concluded that:

* Invitations will be sent out for the first meeting of the ad-hoc working group, which will convene on 17 April;
* The next videoconference will be planned in close cooperation with the Croatian Presidency; it will still be decided whether the next meeting in this format is needed before or after the pledging event. The next meeting will also serve to report back from the ad-hoc working group, the hackathon, and the outreach to international partners.