

2nd meeting of the ERAvsCorona Ad hoc group with EU Member States

6 July 2020 9.00-10.30

Draft minutes

The meeting was chaired by [REDACTED] 5.1.2e

The main objectives of the meeting were to provide an overview of the outcomes of the various subgroups, and agree about the next steps, as regards the four sub-groups and the Ad hoc group. It was also an opportunity to share information on relevant EU COVID-19 activities, mostly on the R&I side.

The Chair presented the EU Strategy for COVID-19 vaccines (presentation in Annex). The Strategy is a couple of weeks old, but already triggered intense discussions with vaccine producers regarding how to secure sufficient production of vaccines in the EU and sufficient supplies for its Member States. For confidentiality reasons, no information can be shared at this stage with this group regarding discussions on Advance Purchase Agreements with vaccine producers, for support via the EU Emergency Support Instrument.

In terms of support to R&I, the Chair specifically highlighted:

- (i) the €1 billion pledged by the EC for the development of vaccines, treatments, and tests via a number of instruments in the broader context of the Coronavirus Global Response,
- (ii) funding research projects and teams across Europe and beyond (via collaborative research, the European and Developing Countries Clinical Trials Partnership (EDCTP), the Innovative Medicines Initiative (IMI), the European Innovation Council (EIC), and InnovFin financing tools),
- (iii) the ERAvsCorona Action Plan developed in collaboration with R&I national ministries.

The Chair reminded the Ad hoc group of the leading role of the EU in the Coronavirus Global Response, a multilateral effort with European and international partners, brought forward in a global fashion, with €15.9 billion raised so far with a view to providing fair and universal access to vaccines.

The Chair also presented the progress on the 10 actions identified in the ERAvsCorona action plan:

1. Coordination of R&I funding against the Coronavirus

The ad-hoc working group was set up to create effective European pipelines for vaccine, therapy and diagnostic developments from research to deployment, gathering DGs R&I/SANTE/JRC, all Member States + Switzerland, Norway, the European Medicines Agency (EMA), the European Centre for Disease Control (ECDC) and the European Investment Bank (EIB). Four subgroups were established and met several times between 17 April and early June.

2. Extending and supporting large EU-wide clinical trials for clinical management of Coronavirus patients

This action is to collect enough evidence about what works and what does not, and avoid fragmentation of study initiatives, so that studies enrol a sufficient number of patients, and use standardized and agreed upon protocols to reach conclusive results on efficacy.

This action is supported by the sub-group on clinical trials and the development of a pan-European clinical trials platform, with dedicated funding (capitalizing on the Discovery trial, the REMAP-CAP trial as well as a Nordic trial). The set up of the adaptive platform is geared to repurposing any potential substance active against the virus, but a branch will also be set up when it comes to vaccines development.

Internationally, collaboration on clinical trials takes place with the EDCTP, which launched 3 calls in April. Collaboration also takes place through the International Clinical Trials Registry Platform of the WHO.

3. 2nd call for an Expression of Interest for innovative and rapid health-related approaches to respond to COVID-19 and to deliver quick results for society for a higher level of preparedness of health systems

This call aims at strengthening capacity to manufacture and deploying readily available solutions in order to rapidly address the pressing needs. It will also improve understanding of the behavioural and socio-economic impacts of the epidemic. The call triggered a strong response from the research community, with 454 proposals submitted in just over three weeks. The results are expected to be announced by mid-August. It is clear at this stage that not all excellent projects from this call will be funded, so how to carry this forward in the future needs to be kept in mind.

4. Increasing support to innovative companies

This has been via:

- the Horizon 2020 EIC pilot Accelerator addressing Coronavirus-related issues. 93 SMEs which submitted coronavirus-relevant applications were invited to live interviews, and 36 of them were selected for funding, while 139 other excellent proposals will receive a special Coronavirus "Seal of Excellence". The EC hopes that this will help those excellent proposals to be funded at national or regional levels, or possibly also via private foundations;
- increased support to R&I financial instruments addressing coronavirus-related issues, both by Commission and Member States (e.g. EC and EIB agreed a reallocation of €401 million for the InnovFin Infectious Diseases Finance Facility). On 6 July, it was announced that the Commission and EIB provide CureVac with a €75 million financing for vaccine development and expansion of manufacturing, including for CureVac's vaccine candidate against SARS-CoV-2¹.
- the establishment of a Coronavirus EIC Platform for matchmaking services.

5. Creating opportunities for other funding sources to contribute to R&I actions on Coronavirus

This has notably been supported via the award of Seal of Excellence for Coronavirus-relevant innovations by SMEs/startups evaluated as excellent, but not funded under EIC calls. Additional and complementary opportunities for the Seals should be explored, e.g. the funding at national/regional level, or by private foundations.

¹ https://ec.europa.eu/commission/presscorner/detail/en/IP_20_1238

6. Establish a one-stop shop for Coronavirus R&I funding

On 14 May, the EC launched the European Research Area (ERA) corona platform², which is a one-stop shop providing comprehensive information about funding opportunities in relation to Coronavirus at European Union and national level.

7. Establish an ad-hoc High Level R&I Task Force on the Coronavirus – further reflection needed for this action.

8. Access to Research Infrastructures

Many research infrastructures flagged their availability to support COVID-19 research, and refocused their activities. In three cases (for TRANSVAC2 and EVA-GLOBAL grants), the need for top-up budget emerged, to offer specific services to accelerate COVID19 vaccine development (TRANSVAC2), to widely distribute virus/reference materials for SARSCov2 diagnostics (EVA-global) and to carry out SARSCov2 experimental work under high risk pathogen BSL3/4 containment conditions (ERINHA-Advance).

A new action for the development of a Population Health Information Research Infrastructure (PHIRI) has also been proposed as part of the amendment of the Work Programme (Research Infrastructures part).

9. Research data sharing for SARS-CoV-2 and the Coronavirus

A COVID-19 data sharing platform³ was launched by the EC and EMBL-EBI, to facilitate data sharing and analysis in order to accelerate research.

The EC encourages MS/AC to support this activity towards the researchers they are in contact with at national level.

10. Pan-EU Hackathon to mobilise European innovators and civil society

Took place on 24-26 April 2020, with 21000 participants putting forward 2160 solutions. 120 winners were selected and invited to a follow-up matchathon, which took place on 22-25 May, to match-make the winners with partners who will help the solutions to be turned into actual products and services. 40 countries were represented during the Matchathon. 2235 new partnerships were created at the Matchathon to help scaling up the 120 winning projects of the hackathon.

The Chair also mentioned a very thorough portfolio analysis by Commission services of EU-supported collaborative research projects, and projects from the EIC, European Research Council (ERC) and European Institute of Innovation and Technology (EIT). The analysis examined whether projects previously or currently supported already delivered any result that could be useful for addressing the COVID outbreak. Horizon 2020 projects with a potential to contribute to fighting the crisis can be found on the ERA Corona Platform⁴.

² <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/covid-19>

³ <https://www.covid19dataportal.org/>

⁴ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/covid-19?tabId=4>

Work undertaken by the 4 subgroups and the respective outcome was then presented by the EC.

1. Testing

Pilar Aguar Fernandez underlined that the 4 meetings of the group were very well attended, with more than 40 very active participants.

The group focused on knowledge gaps and the most urgent priorities for COVID-19 testing research.

A smaller drafting team was set up, that produced a draft document based on the discussions in the group. Drafts were shared with the rest of the group, and following a few iterations, a very solid document was agreed upon, which identifies major unknowns in the field.

The document is to be presented at the R&I Directors-General meeting on Wednesday 8 July, and should serve as guidance for the EU and countries notably regarding calls that could be launched.

The document will be shared with the Ad hoc group.

2. Clinical trials

5.1.2e presented the work of the subgroup, which focused on the need for an EU-wide clinical trials network (adaptive platform trials). The group highlighted the importance of (i) harmonised protocols and data collection, (ii) an integrated approach, clinical trial coordination & regulatory authorities & ethics experts, and (iii) early exchanges on planned trials.

For the moment the platform is focused on repurposing of therapeutics, however it is now moving to vaccines.

A schematic overview of the network based on Adaptive Platform Trials was provided, which is ultimately expected to deliver new therapeutic indications, therapies, clinical guidelines and vaccines. Discussions now need to take place regarding the governance of this network, including the respective roles of envisaged Scientific steering committee and Strategic steering committee. Such discussions should be lifted over to more official comitology or expert groups channels, such as via the Programme Committee, or the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP).

It was underlined that the work of this subgroup around the mechanics of this adaptive trials platform very much contributed to action 2 of the ERAvsCorona Action Plan, as it informed the way the EC mobilised additional funding. It will similarly feed the reflection when the work is extended to vaccines.

3. Manufacturing

DDG Seychell from DG SANTE who was leading this subgroup took another position, and the outcome was presented by Loukianos Gatzoulis.

The subgroup gathered in 3 well-attended meetings.

The mandate of the subgroup was to determine the manufacturing capacities available in EU for COVID-19 vaccines, tests and treatments. From the 1st meeting, it was agreed to focus on manufacturing capacities for vaccines. The group also discussed criteria for the selection of vaccine candidates.

A set of questions was formulated to identify manufacturing facilities/capacity in EU/EEA that produce or can be re-purposed to produce human vaccines/medicines.

Information about manufacturing capacity for vaccines was obtained from the Pharmaceutical Committee and Heads of Medicines Agencies.

In parallel, a process developed at EC level, led by the Secretariat-General, aimed to identify means for manufacturing vaccines through the private pharma sector.

The information gathered in this subgroup supported the EU Strategy for COVID-19 vaccines.

As we are at the very early stages of determining the availability to produce & scale up vaccine candidates, all options should be kept open and the list of criteria reviewed in due time, as some candidates might be easier to develop and produce than others.

Relevant 'manufacturing' information from the Pharmaceutical Committee will be made available to the extent possible (non-confidential information). Information pertaining to discussions with large pharma companies will not be shared, as this information is confidential and cannot be disclosed.

It was underlined that the challenges of manufacturing vaccines, treatments and personal protective equipment resonate not only in terms of R&I (e.g. 2nd Horizon Expression of Interest launched in May) and the future Horizon Europe, but also link to the pharmaceuticals strategy that is currently in development under the lead of DG SANTE.

4. Financing

5.1.2e presented the work under the subgroup, which met 5 times. The objective was to present EU initiatives to MS representatives and discuss how these could be leveraged with national initiatives. Were discussed amongst others: the EIC Accelerator pilot and COVID-19 call, including the concept of Seal of Excellence; EIB instruments supporting COVID-19 related R&D activities in the life science sector; European Regional Development Funds; Important Projects of Common European Interest; COVID-19 measures under InnovFin SME Guarantee; the EU4Health Programme; the EU Vaccines Strategy.

The possibility of establishing an Important Project of Common European Interest for ramping up of the production facilities for COVID-19 vaccines raised considerable interest.

The chair underlined the appreciation by the EC of all the work done in the subgroups, and invited comments regarding their potential continuation or wrap up. The Chair also stressed that any decision regarding the wrap up of the Ad hoc group operations would be from the group of R&I Directors-General, meeting on Wednesday 8 July. The participants of the Ad hoc group were nevertheless also encouraged to provide their views regarding the potential wrap up of the Ad hoc group's work.

PT thanked the EC for swift reaction to the crisis and for initiating the ERAvsCorona Action Plan; considered subgroups and Ad hoc group as an excellent way to share information, but as another phase of the pandemic develops, it is time to wrap up and continue discussions under other types of groups (DG SANTE, and Council).

ES thanked the Commission, members of the groups and those in charge of the groups in putting together the ideas, which made the work at national level easier.

SK thanked the Commission; underlined the importance of the work under the manufacturing subgroup; supported the continuation of subgroups and of the Ad hoc group.

The Chair concurred on the importance of work related to manufacturing, and underlined the activities related to advance purchase agreements via the Emergency Support Instrument (vaccine by vaccine), as well as the portfolio approach of the Coalition for Epidemic Preparedness Innovations (CEPI) to find solutions for manufacturing all the vaccines. She also mentioned the links to the Global Vaccine Access (COVAX) Facility. Information regarding what has already been done can be circulated, then the reflection will be how to take this work forward through more official channels. Future work will need to consider the type of financing needed to support promising developments.

SE thanked for a really efficient initiative, supported the wrapping up of the Ad hoc group, and underlined interest in the future collaborations on clinical trials.

FIN thanked for a very useful process, which should be continued in one way or another, especially as the crisis is not over yet.

FR thanked the Commission, underlining that the answer to the crisis can only be at European and international levels; stressed the importance to share the outcomes of the subgroups with all MS, as broadly as possible; recognized the value of the subgroups and the Ad hoc group, but could not yet provide a position regarding their potential wrap up.

DK thanked for the work, and asked that the groups be discontinued and that the discussions be brought under official channels such as Programme Committee, SGPP and/or Council groups.

CH thanked for the work and concurred that it is time to wrap up the groups and use established structures.

BG thanked all for the great work in the groups, and highlighted especially the outcomes of the testing group; provided support to maintaining the Ad hoc group, seen as important at national level; underlined the interest to access information from other groups.

PL thanked for the efforts and the work accomplished in a very timely fashion; underlined that efforts should now be directed to existing groups, and that subgroups should be wrapped up.

IT thanked for the work and stressed that it will be important in the future to explore the relationships between what is done at European level and at national level, which would help using research in a better way.

MT thanked for the work and underlined the importance of information regarding manufacturing capacities in Europe.

The Chair noted mixed messages received from delegations regarding the closure of subgroups; the general acknowledgment that further work is still needed, but that this might go via existing groups (such as comitology and experts groups); and the recognition of the usefulness of subgroups to exchange information between countries. The Chair suggested that Directors-General be informed on 8 July that the Ad hoc group generally agreed that it would be timely to close down the subgroups, but calls for one additional meeting of the Ad hoc group to take stock of work over the summer, of the portfolio analysis, and to examine how the work done so far could then be taken over by other groups.

IT supported this approach, highlighting the importance to keep information exchange between ministries at national level, for which the Ad hoc group is a good platform; agreed that a re-evaluation in September would be appropriate.

SE and FIN supported the proposal of the Chair.

SLO thanked for the work done so far under exceptional circumstances, and mentioned that work now has to continue via the regular channels, underlining that these are entitled to take decisions; supported the approach proposed by the Chair.

AT thanked the Commission for setting up the working groups, which accomplished a lot of work; supported the proposal to wrap up the subgroups, and have another Ad hoc group meeting to take stock of work done over the summer, then decide which other groups can take over via comitology.

DK welcomed a sensible suggestion by the Chair regarding the decision by Directors-General whether to continue the work of the Ad hoc group, including a potential meeting after the summer; underlined that DK doesn't agree to an Ad hoc group continuation and does not want it to become a formalized structure.

PT and CH supported DK.

The Chair then suggested that Directors-General be proposed two options for decision: i) wrap up the Ad hoc group, or ii) hold an additional meeting in September (as previously mentioned).

IRL and RO supported that both options be tabled to the Directors-General.

Conclusions

When it comes to the continuation of the subgroups, there was general agreement that these groups have delivered as much as could be under this configuration. It was proposed that any potential further work in the area of the subgroups should be undertaken using the usual channels for decision-making at EU level, i.e. using regular comitology (Programme Committee), expert groups (such as SANTE's Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP) or other expert groups in DG SANTE) or relevant Council groups.

Regarding a potential wrapping up the work of the Ad hoc group, the decision to do so would be for the group of R&I Directors-General. Two options will be tabled at the meeting of R&I Directors-General on 8 July 2020, for decision-making:

- wrap up the Ad hoc group
- or
- hold an additional Ad hoc group meeting in September, to examine work done over the summer, decide what further work needs to be carried out and assess how remaining work could be taken over through formal channels.

The Commission will follow up whatever decisions is taken by Directors-General on 8 July 2020.

Slides of this meeting and relevant documents of the subgroups will be circulated.

The Chair concluded the meeting by underlining the appreciation of the Commission that Member States found meaningful the work delivered in these extraordinary circumstances. She underlined that the ongoing pandemic calls for additional work.